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Kooij et al.

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(54) **ADJUSTABLE HEADGEAR TUBING FOR A PATIENT INTERFACE**

(71) Applicant: **ResMed Pty Ltd**, Bella Vista (AU)

(72) Inventors: **Michiel Kooij**, Sydney (AU); **Alexander Joel Bentley**, Sydney (AU); **Igor Besic**, Sydney (AU); **Robert Thomas Burnham**, Sydney (AU); **Aaron Samuel Davidson**, Sydney (AU); **Priyanshu Gupta**, Sydney (AU); **Kirrily Michele Haskard**, Sydney (AU); **Ryan Michael Kirkpatrick**, Sydney (AU); **Luke Emmanuel Klinkenberg**, Sydney (AU); **Dimitri Marco Maurer**, Gosford (AU); **Joseph Samuel Ormrod**, Sydney (AU); **Gerard Michael Rummery**, Woodford (AU); **Rupert Christian Scheiner**, Sydney (AU); **Bishavjot Singh**, Sydney (AU); **Christopher James Smith**, Sydney (AU); **Lochlan Von Moger**, Sydney (AU); **Paul Derrick Watson**, Sydney (AU); **Daniel Marc Weiss**, Sydney (AU); **Hadley White**, Sydney (AU)

(73) Assignee: **ResMed Pty Ltd**, Bella Vista (AU)

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§ 371 (c)(1),
(2) Date: **Jul. 11, 2018**

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PCT Pub. Date: **Jul. 27, 2017**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Mar. 30, 2016 (AU) 2016901163
Jan. 20, 2017 (WO) PCT/AU2017/050044

(51) **Int. Cl.**
A61M 16/06 (2006.01)
A61M 16/08 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 16/0683*** (2013.01); ***A61M 16/06*** (2013.01); ***A61M 16/0622*** (2014.02);
(Continued)

(58) **Field of Classification Search**
CPC A61M 16/0683; A61M 16/06; A61M 16/0622; A61M 16/0883; A61M 16/0816;
(Continued)

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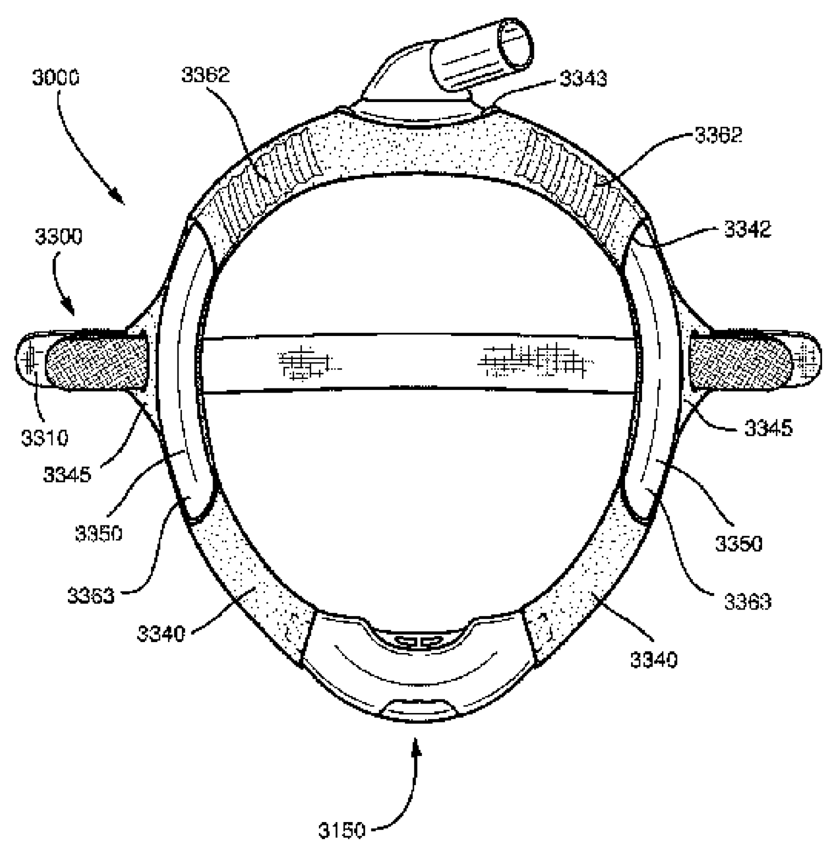
Primary Examiner — Joseph D. Boecker
Assistant Examiner — Thomas W Greig
(74) *Attorney, Agent, or Firm* — Nixon & Vanderhye P.C.

(57) **ABSTRACT**

Aspects of the present technology comprise a positioning and stabilising structure to hold a seal-forming structure in a therapeutically effective position on a head of a patient. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the
(Continued)



entrance of a patient's airways via the seal-forming structure. The at least one gas delivery tube may be constructed and arranged to contact, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head. The positioning and stabilising structure may comprise an adjustment mechanism for adjustment of a length of the at least one gas delivery tube to enable the positioning and stabilising structure to fit different size heads. The positioning and stabilising structure may comprise a bias mechanism to impart a biasing force along at least a part of a length of the at least one gas delivery tube to urge the seal-forming structure towards the entrance of the patient's airways in use.

30 Claims, 43 Drawing Sheets

(51) **Int. Cl.**

A61M 16/00	(2006.01)
A61M 16/16	(2006.01)
A61M 16/10	(2006.01)
A61M 16/12	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 16/0666*** (2013.01); ***A61M 16/0816*** (2013.01); ***A61M 16/0875*** (2013.01); ***A61M 16/0883*** (2014.02); *A61M 16/0066* (2013.01); *A61M 16/109* (2014.02); *A61M 16/125* (2014.02); *A61M 16/16* (2013.01); *A61M 2016/0021* (2013.01); *A61M 2016/0027* (2013.01); *A61M 2016/0039* (2013.01); *A61M 2202/0208* (2013.01); *A61M 2205/0216* (2013.01); *A61M 2205/15* (2013.01); *A61M 2205/3375* (2013.01); *A61M 2205/3653* (2013.01); *A61M 2205/583* (2013.01); *A61M 2205/6063* (2013.01); *A61M 2210/0618* (2013.01); *A61M 2210/0625* (2013.01)

(58) **Field of Classification Search**

CPC A61M 16/0875; A61M 16/0666; A61M 16/08

See application file for complete search history.

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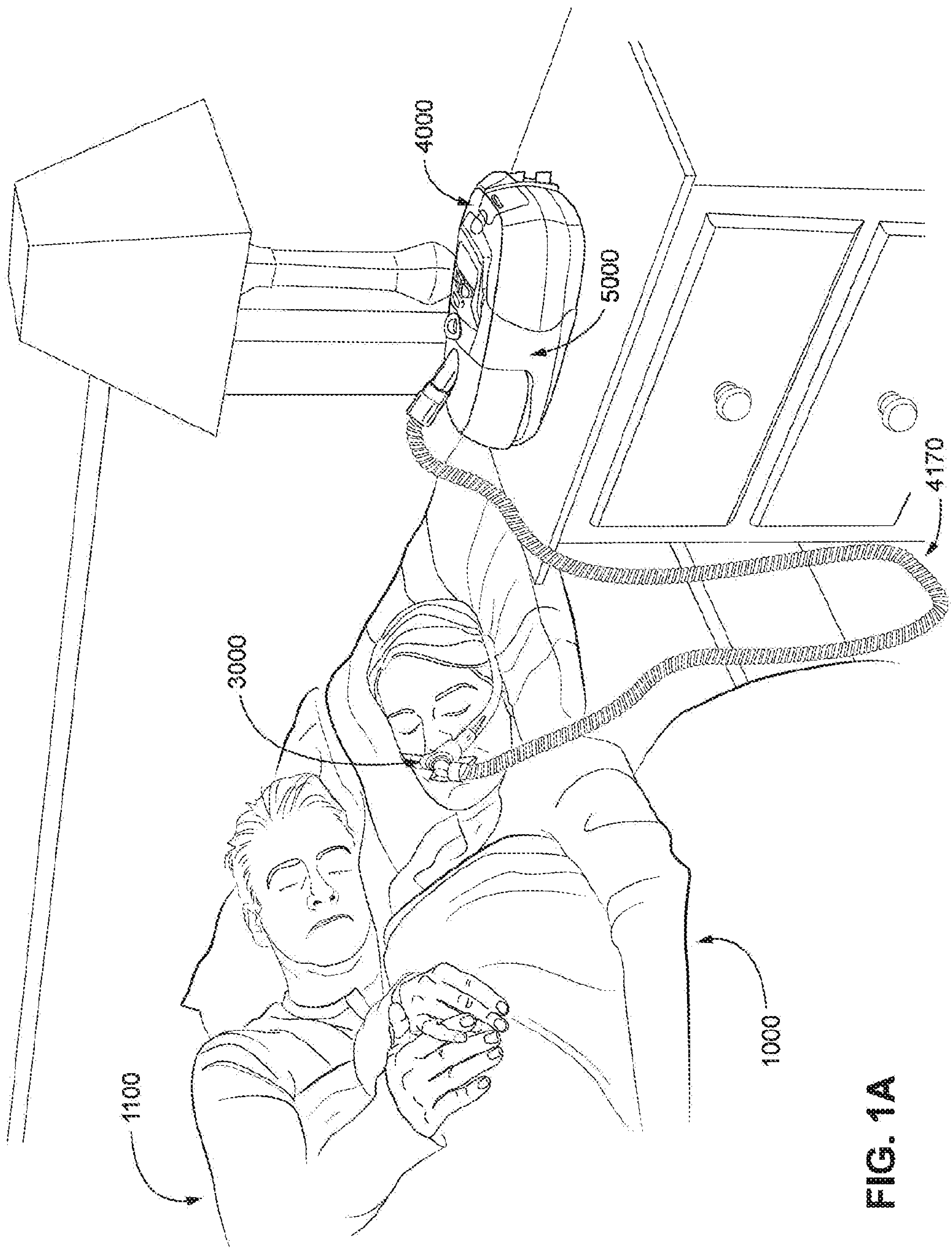


FIG. 1A

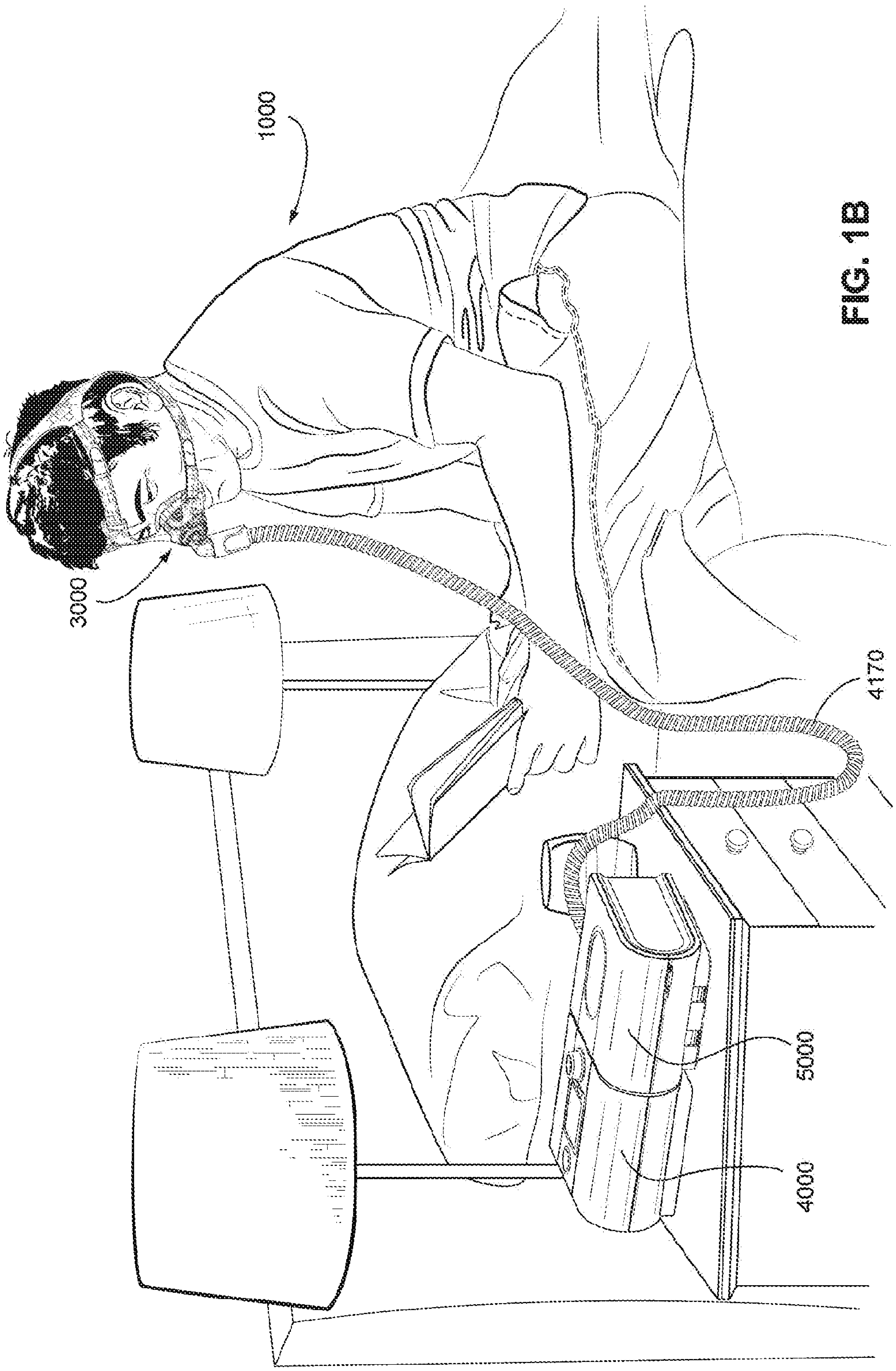
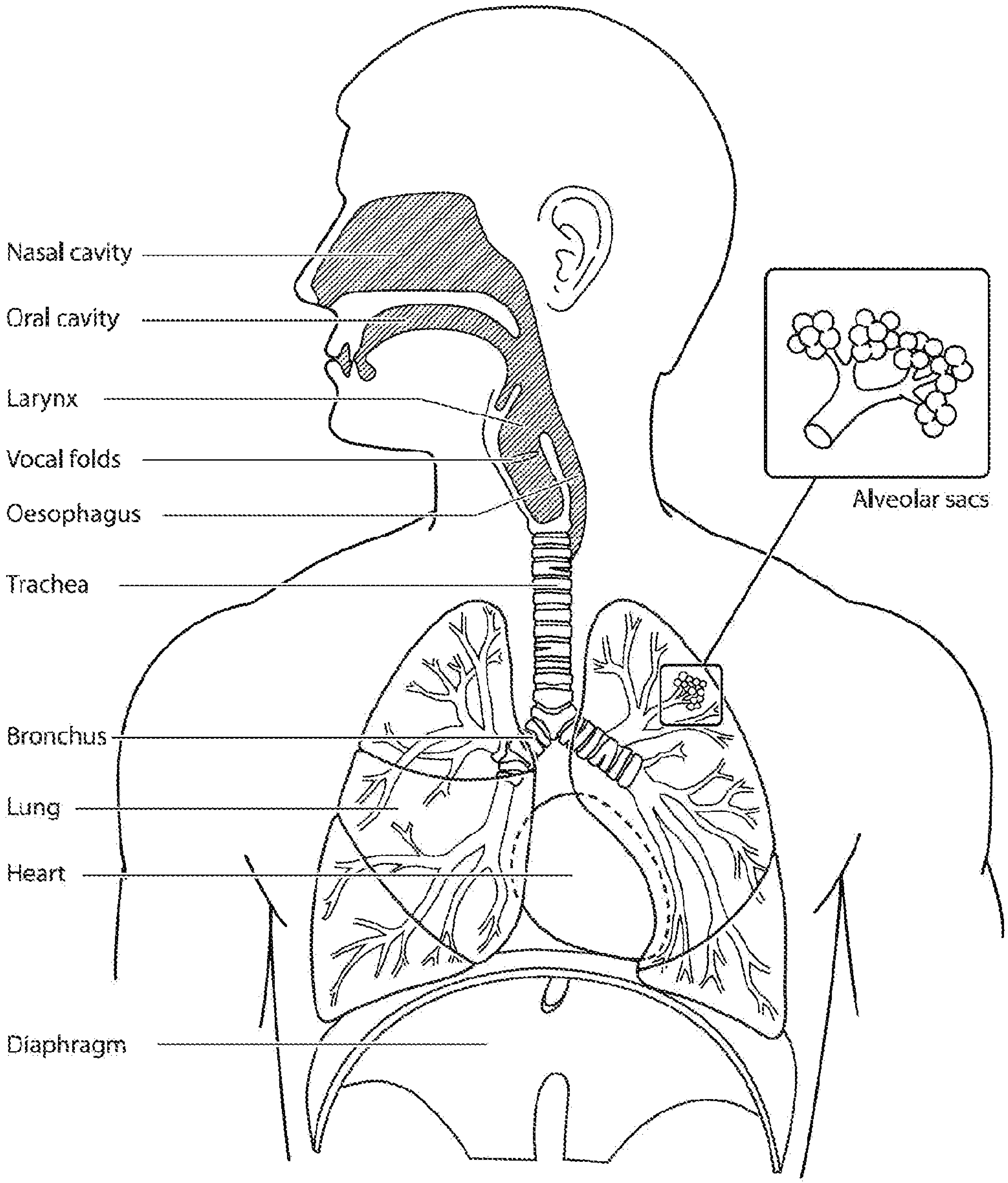


FIG. 1B

FIG. 1C



Nasal cavity
Oral cavity
Larynx
Vocal folds
Oesophagus
Trachea
Bronchus
Lung
Heart
Diaphragm
Alveolar sacs

FIG. 2A

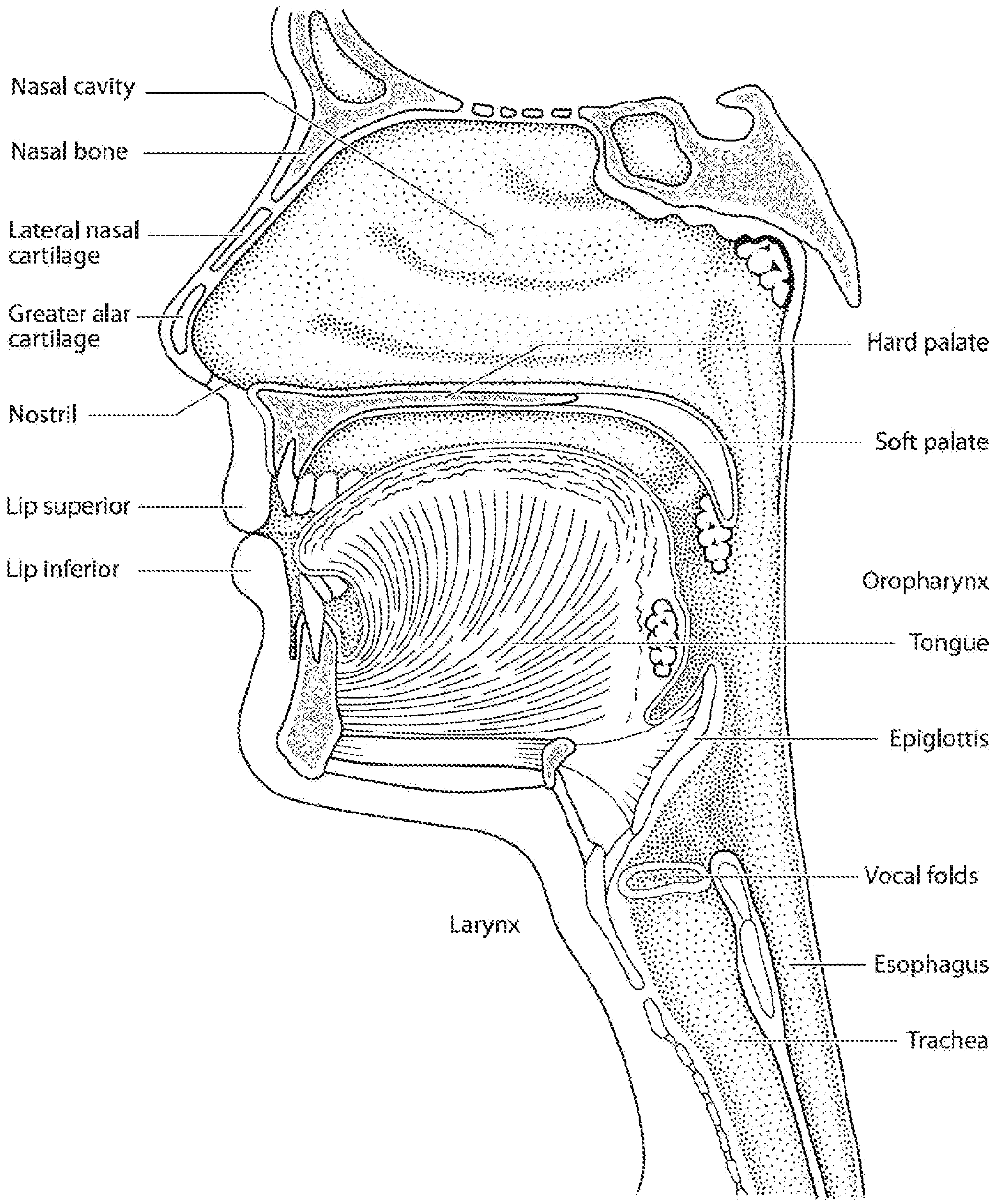
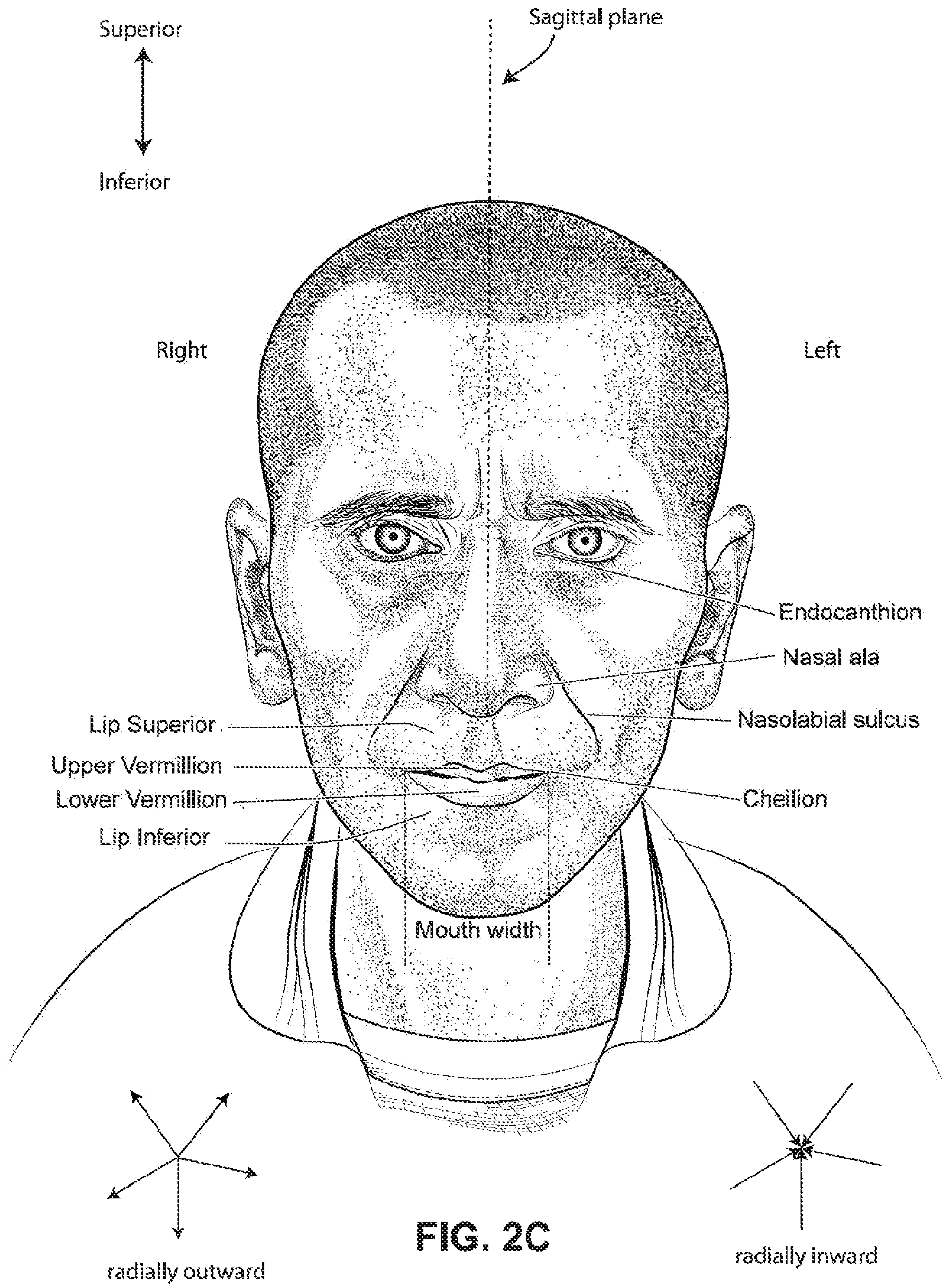

Nasal cavity
Nasal bone
Lateral nasal cartilage
Greater alar cartilage
Nostril
Lip superior
Lip inferior
Hard palate
Soft palate
Oropharynx
Tongue
Epiglottis
Vocal folds
Esophagus
Trachea
Larynx

FIG. 2B



Superior
Inferior
Sagittal plane
Right
Left
Endocanthion
Nasal ala
Nasolabial sulcus
Lip Superior
Upper Vermillion
Lower Vermillion
Cheilion
Lip Inferior
Mouth width
radially outward
radially inward

FIG. 2C

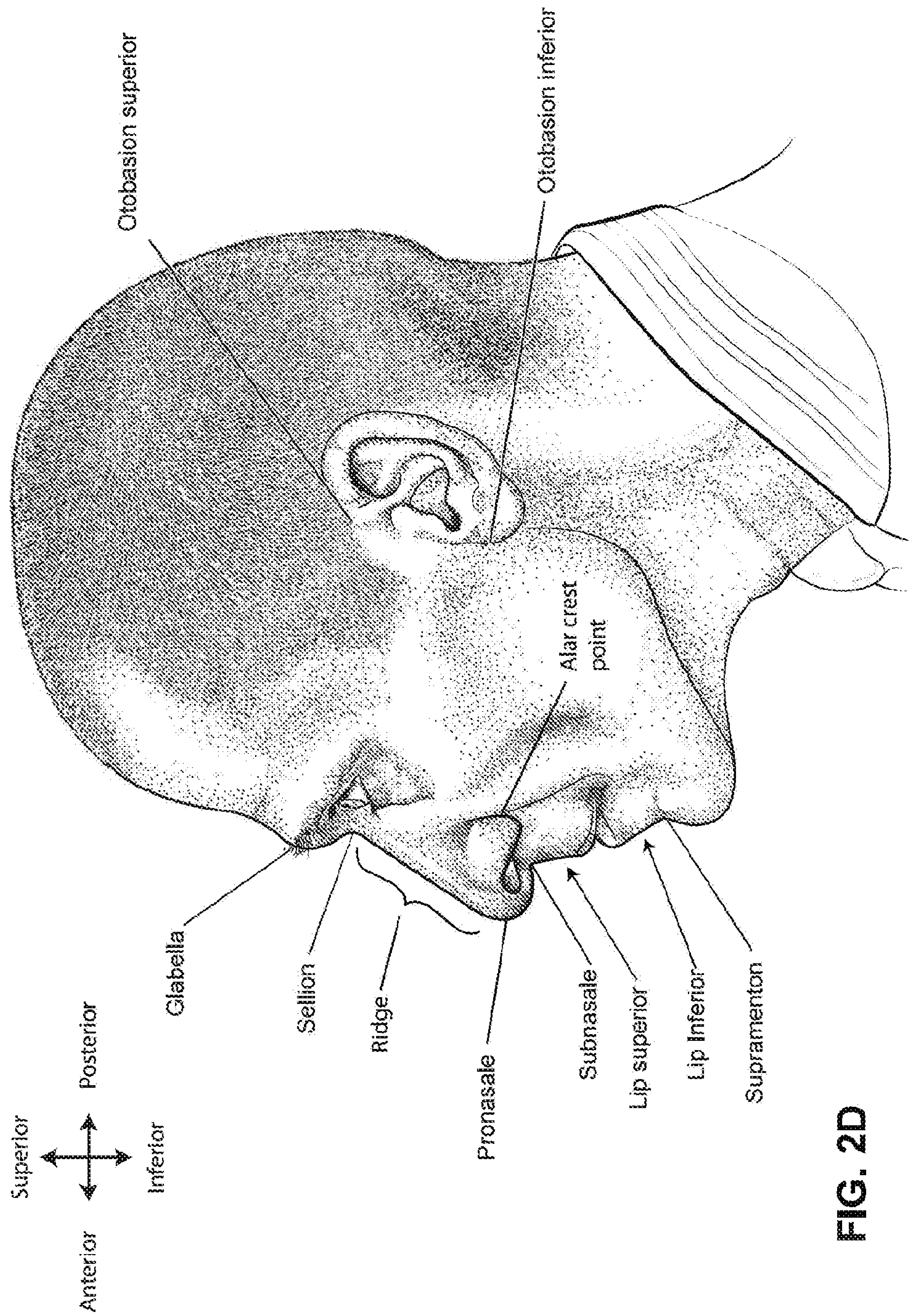

Otobasion superior
Otobasion inferior
Alar crest point
Glabella
Sellion
Ridge
Pronasale
Subnasale
Lip superior
Lip Inferior
Supramenton
Superior
Posterior
Inferior
Anterior

FIG. 2D

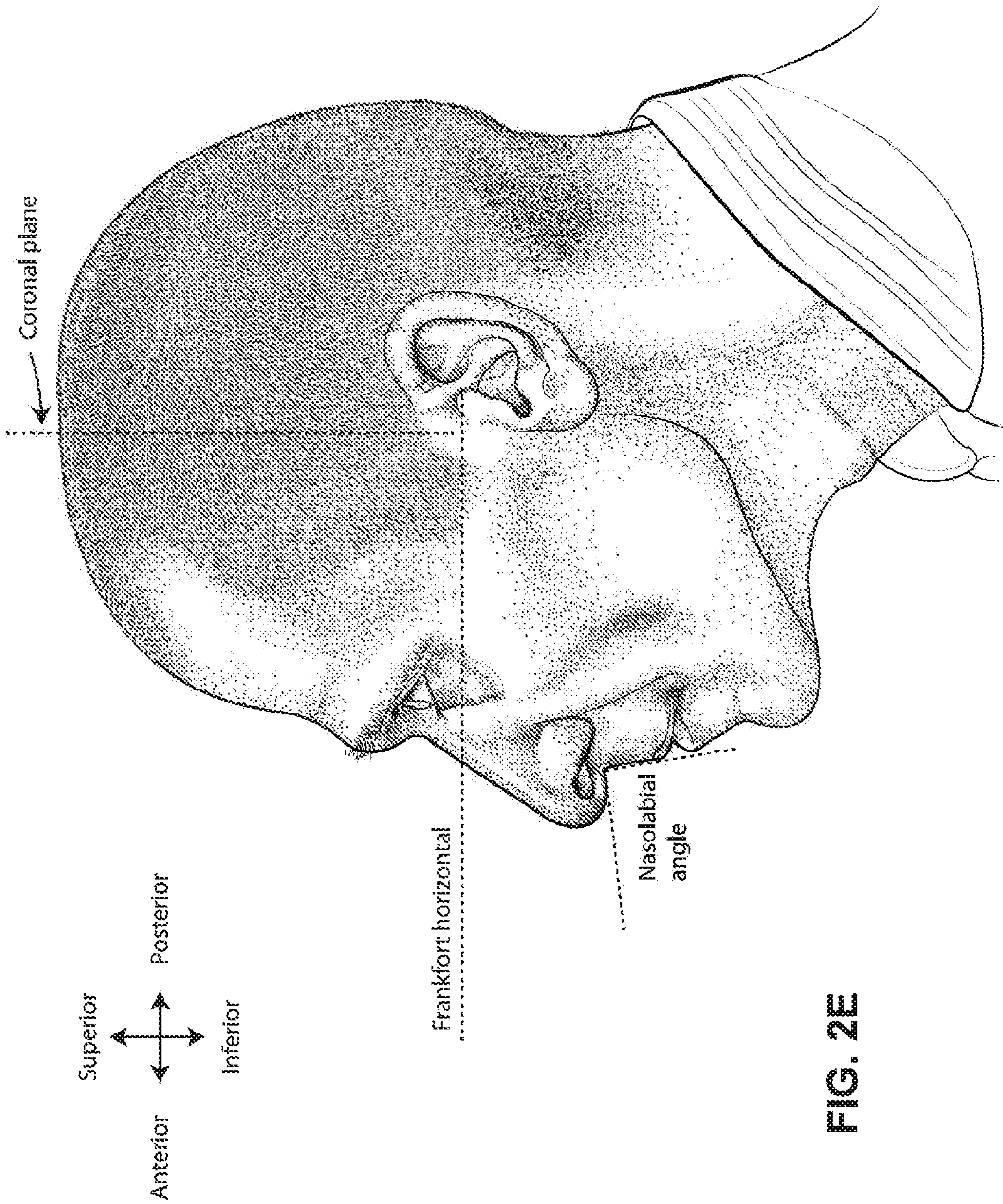

Coronal plane
Frankfort horizontal
Nasolabial angle
Superior
Posterior
Inferior
Anterior

FIG. 2E

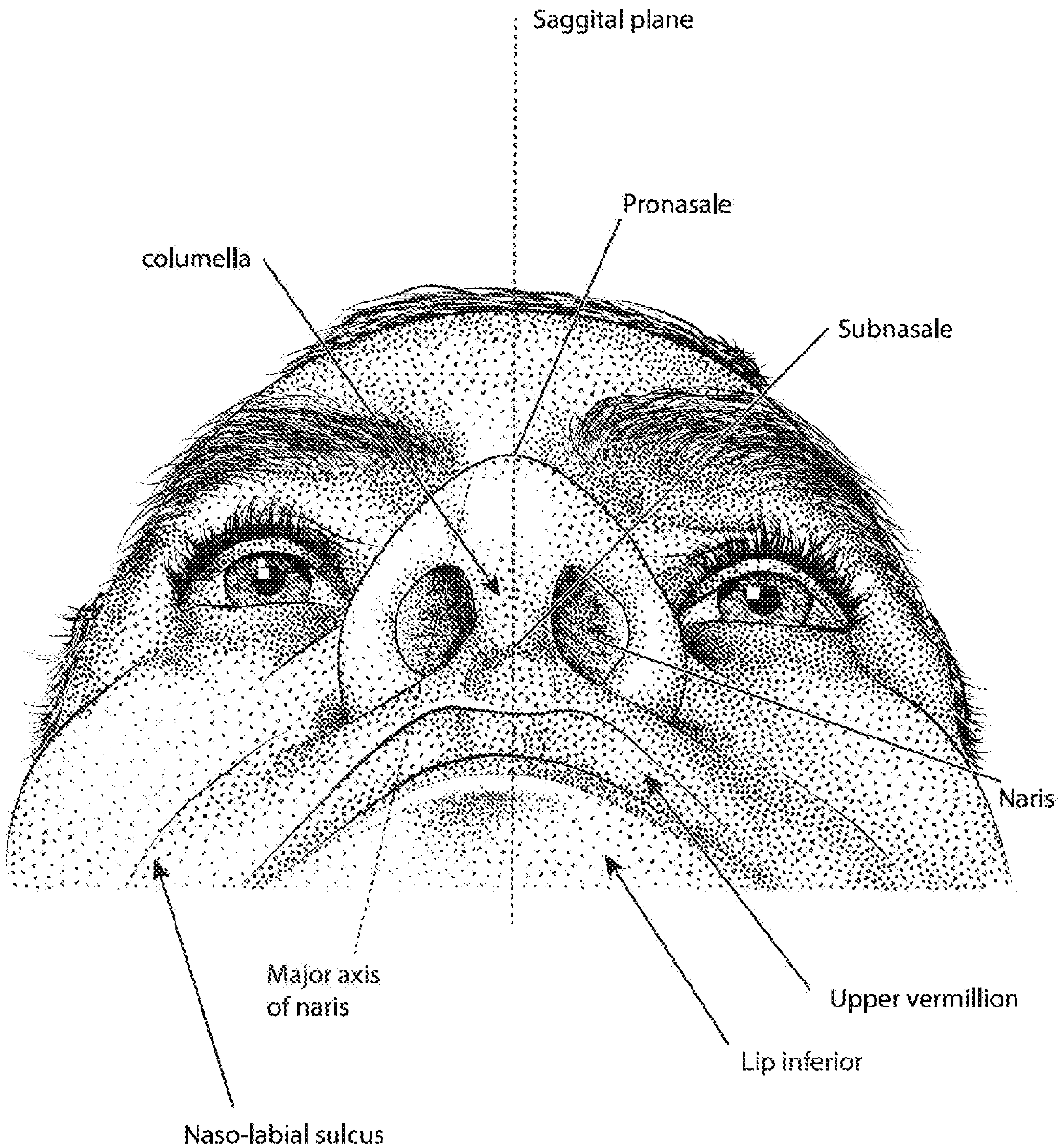
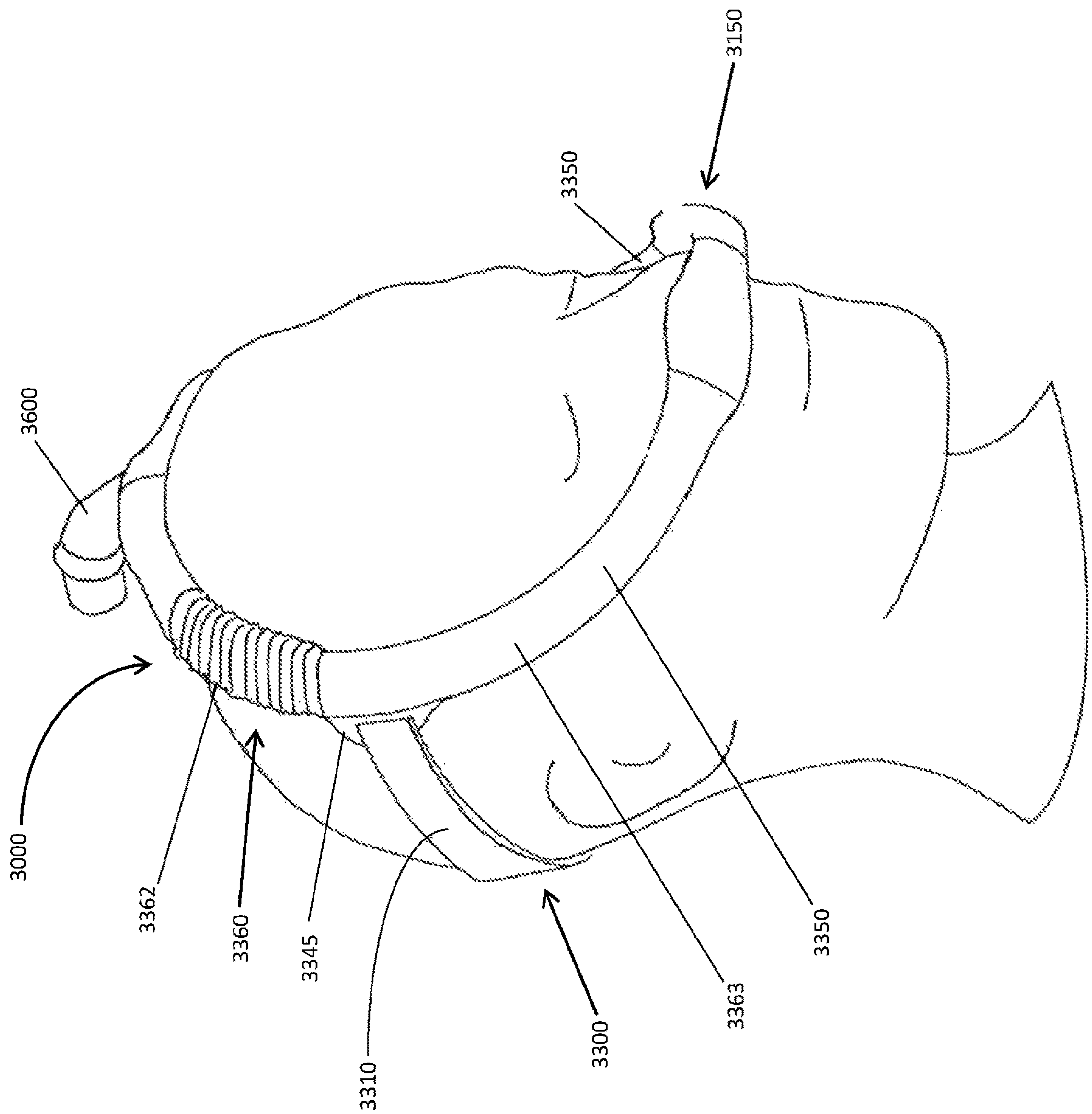

Saggital plane
Pronasale
columella
Subnasale
Naris
Major axis
of naris
Upper vermillion
Lip inferior
Naso-labial sulcus

FIG. 2F

FIG. 3A



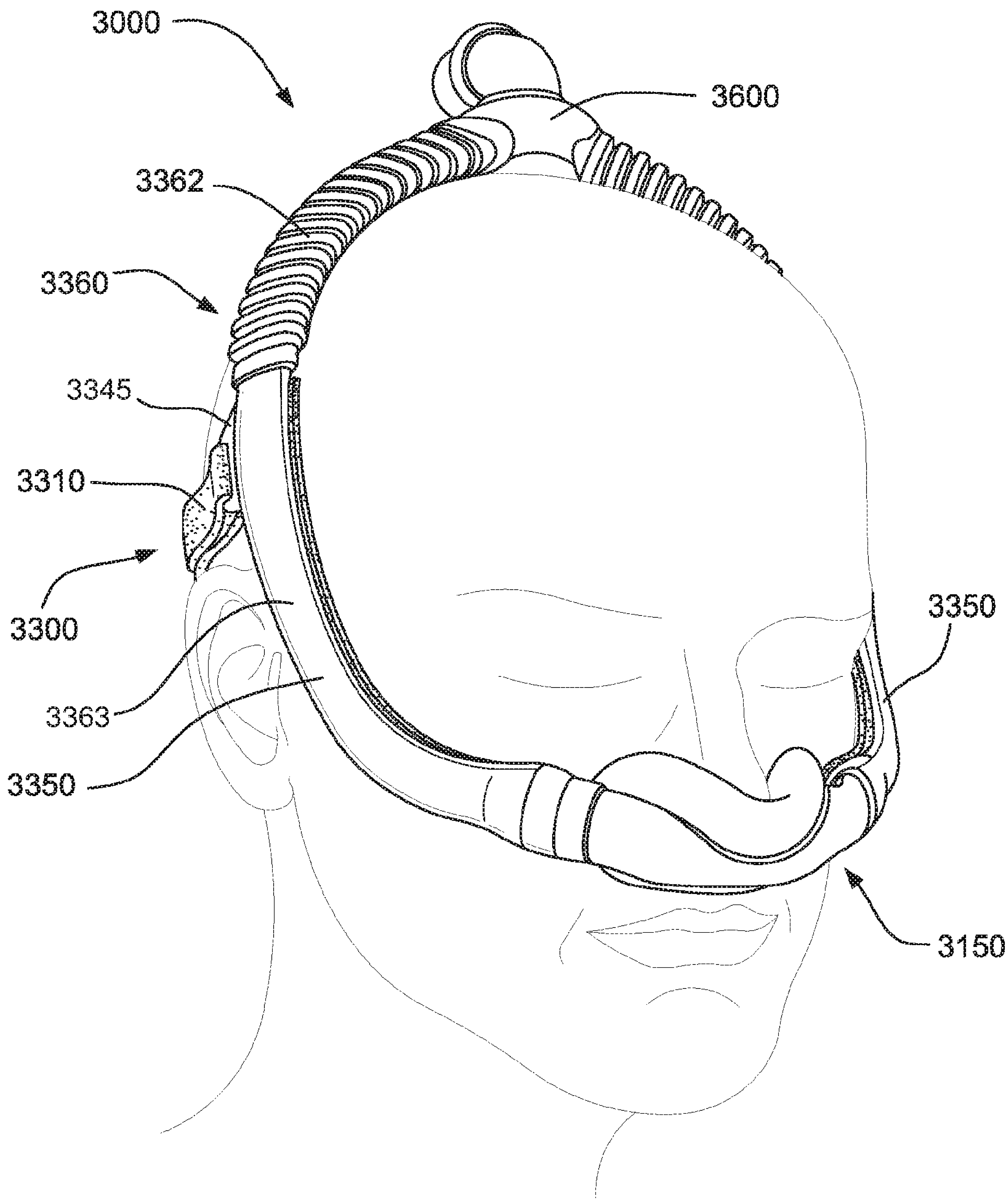


FIG. 3B

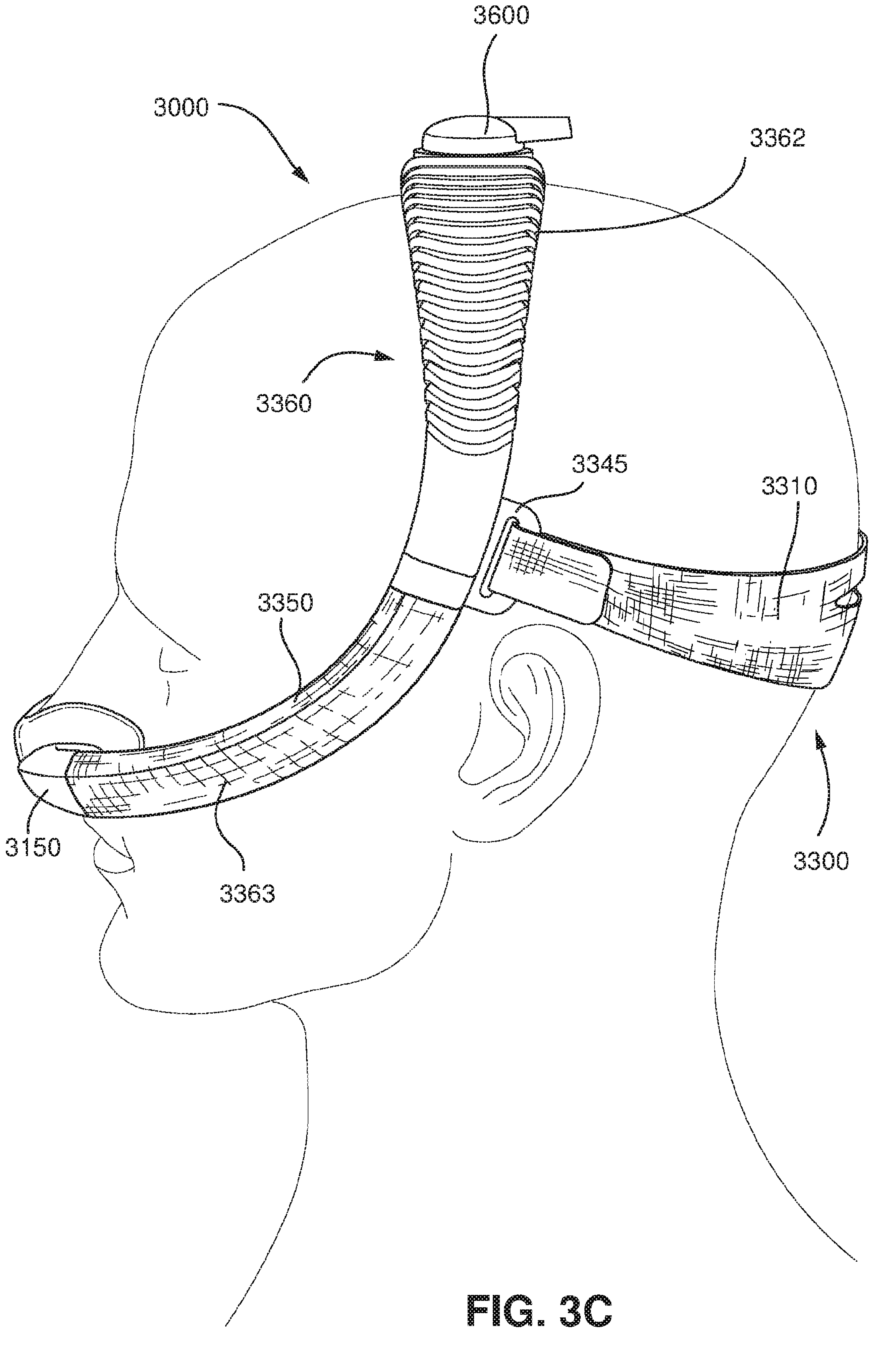


FIG. 3C

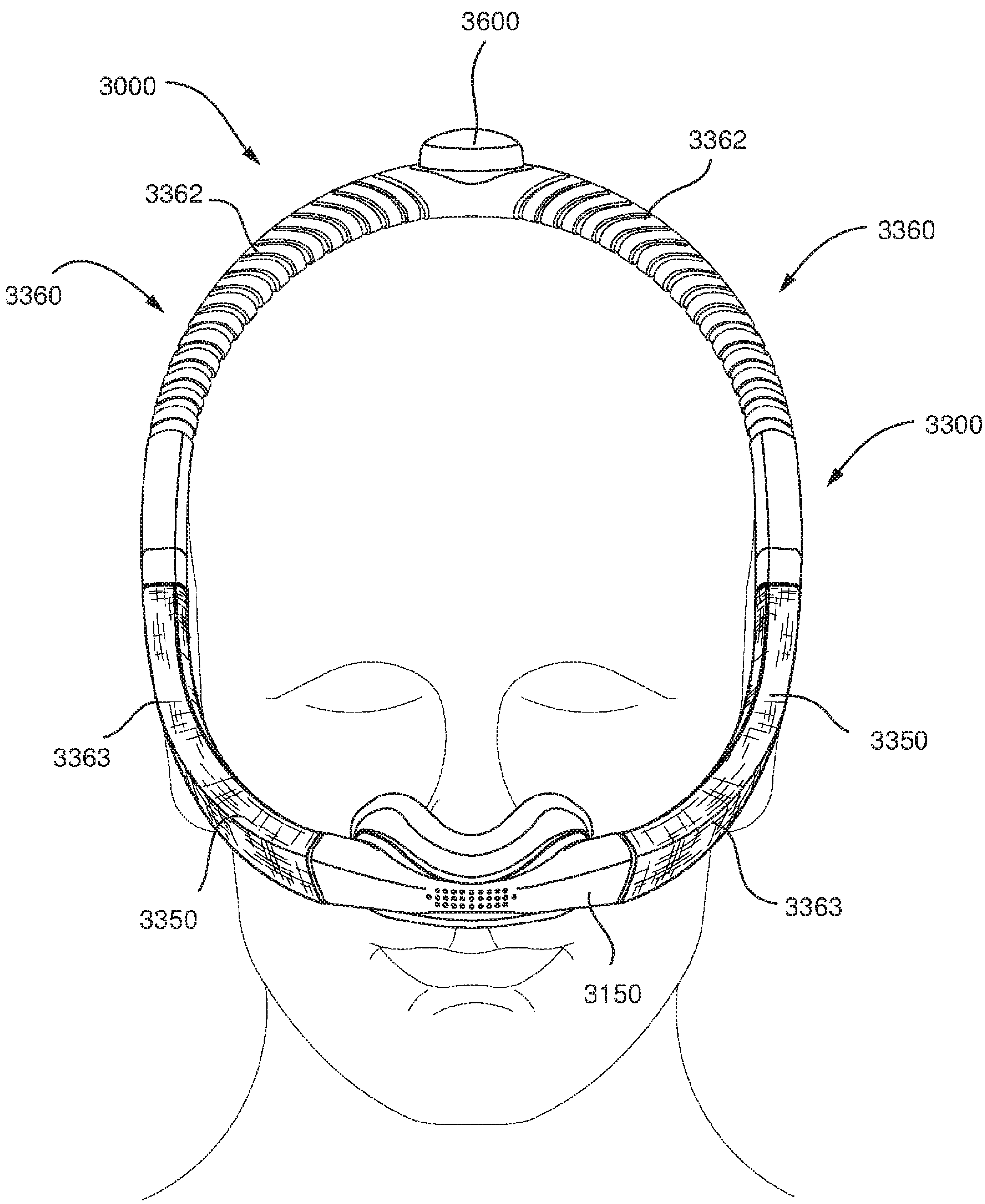


FIG. 3D

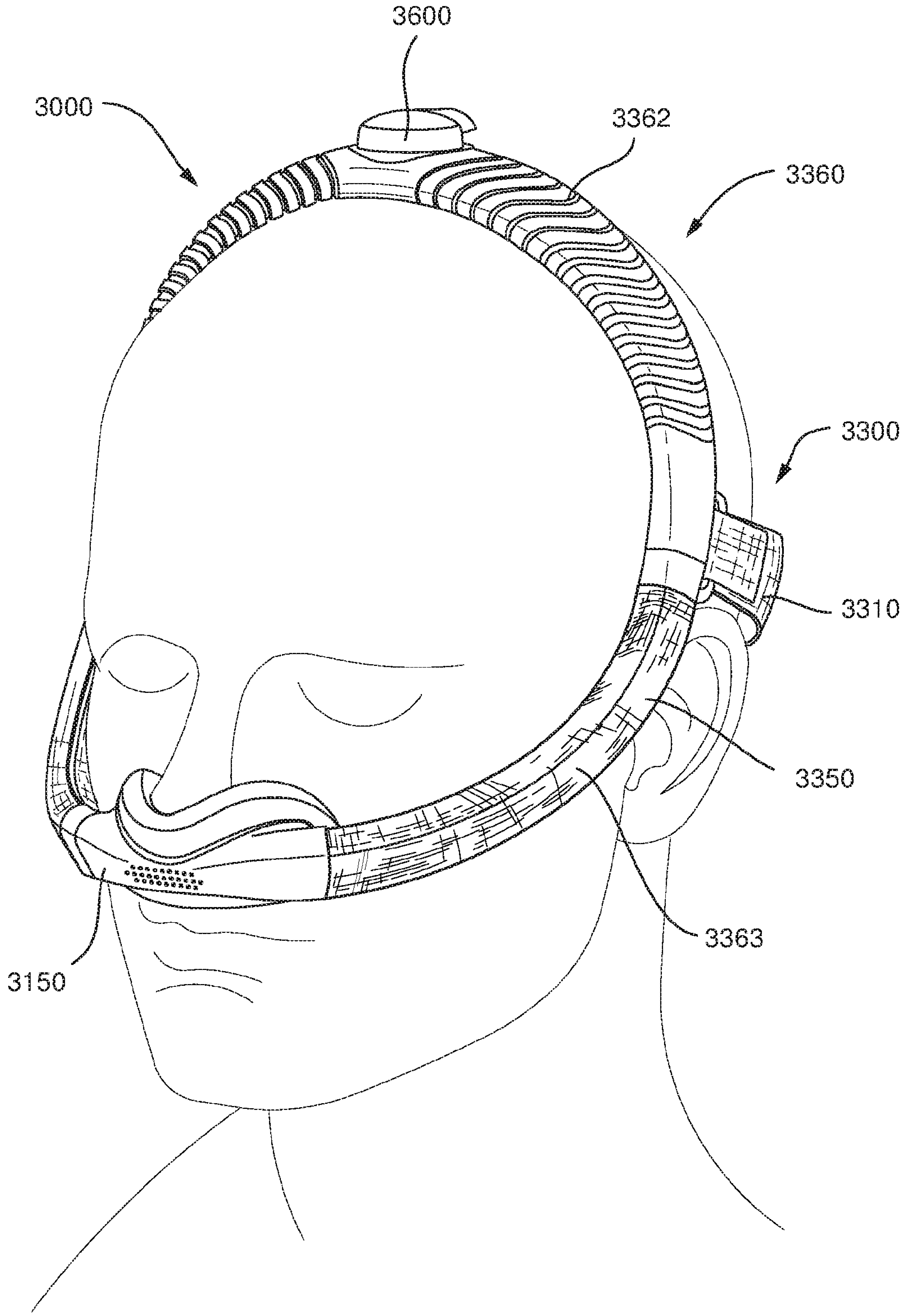
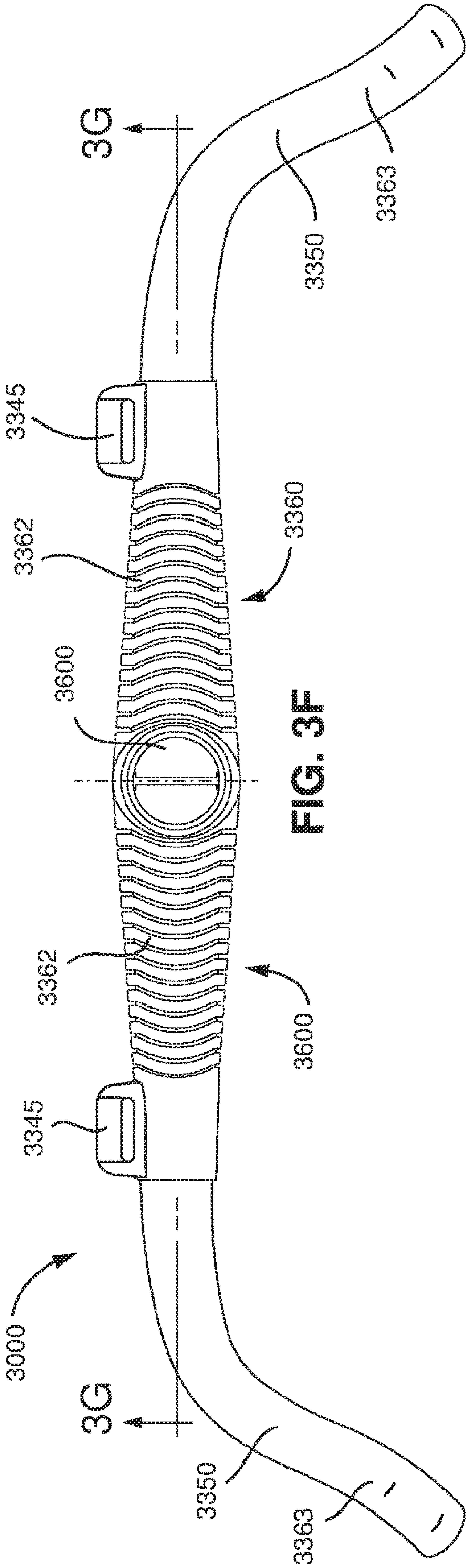


FIG. 3E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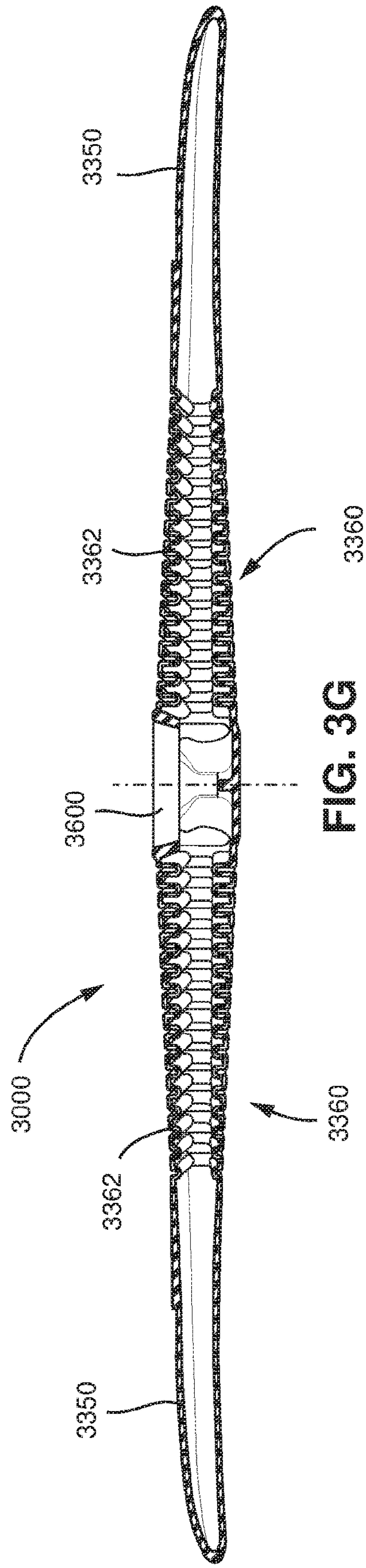
3345
3360
3362
3600
3362
3600
3345
3000
3G
3350
3363

FIG. 3F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3000
3360
3362
3350

FIG. 3G

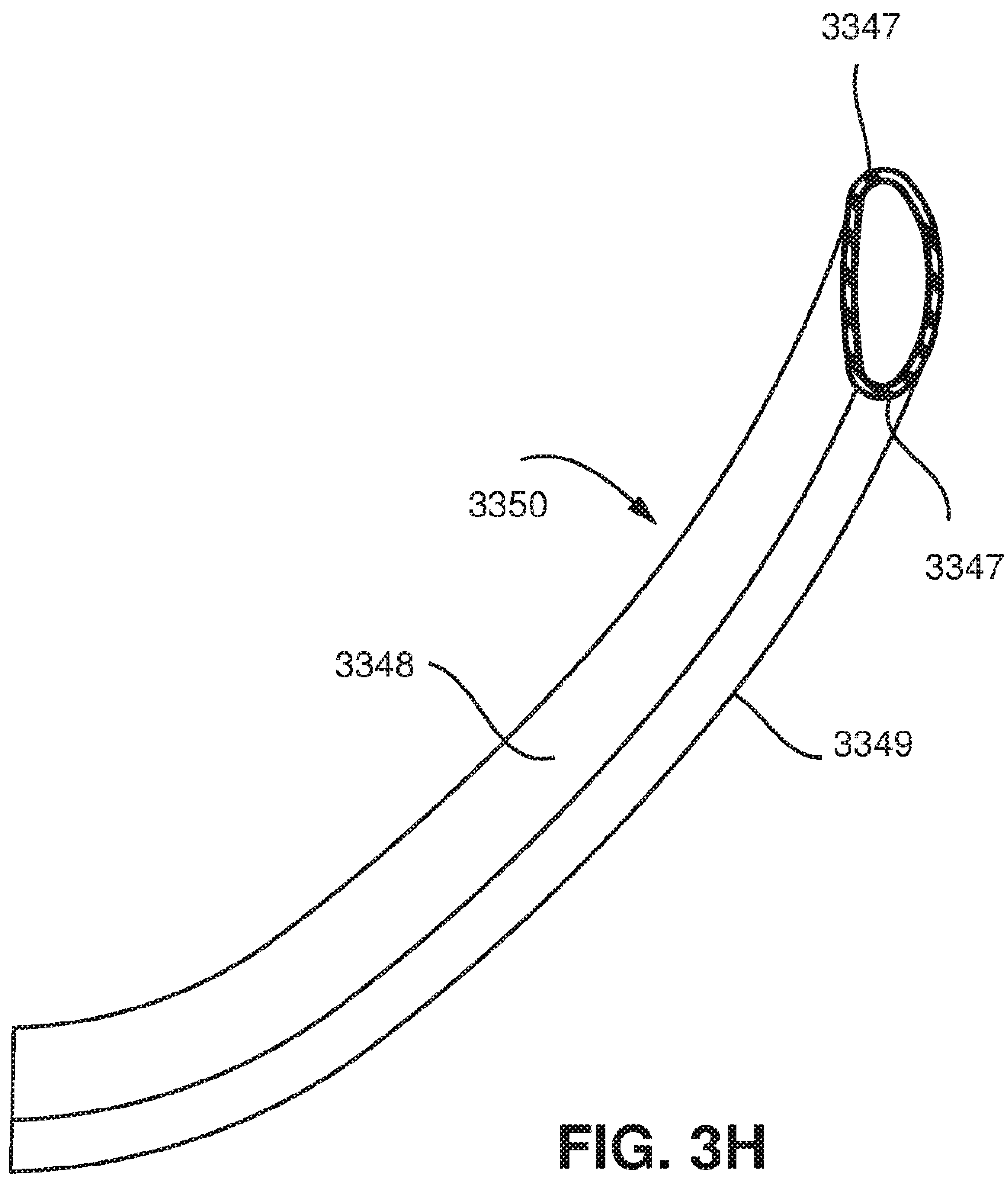
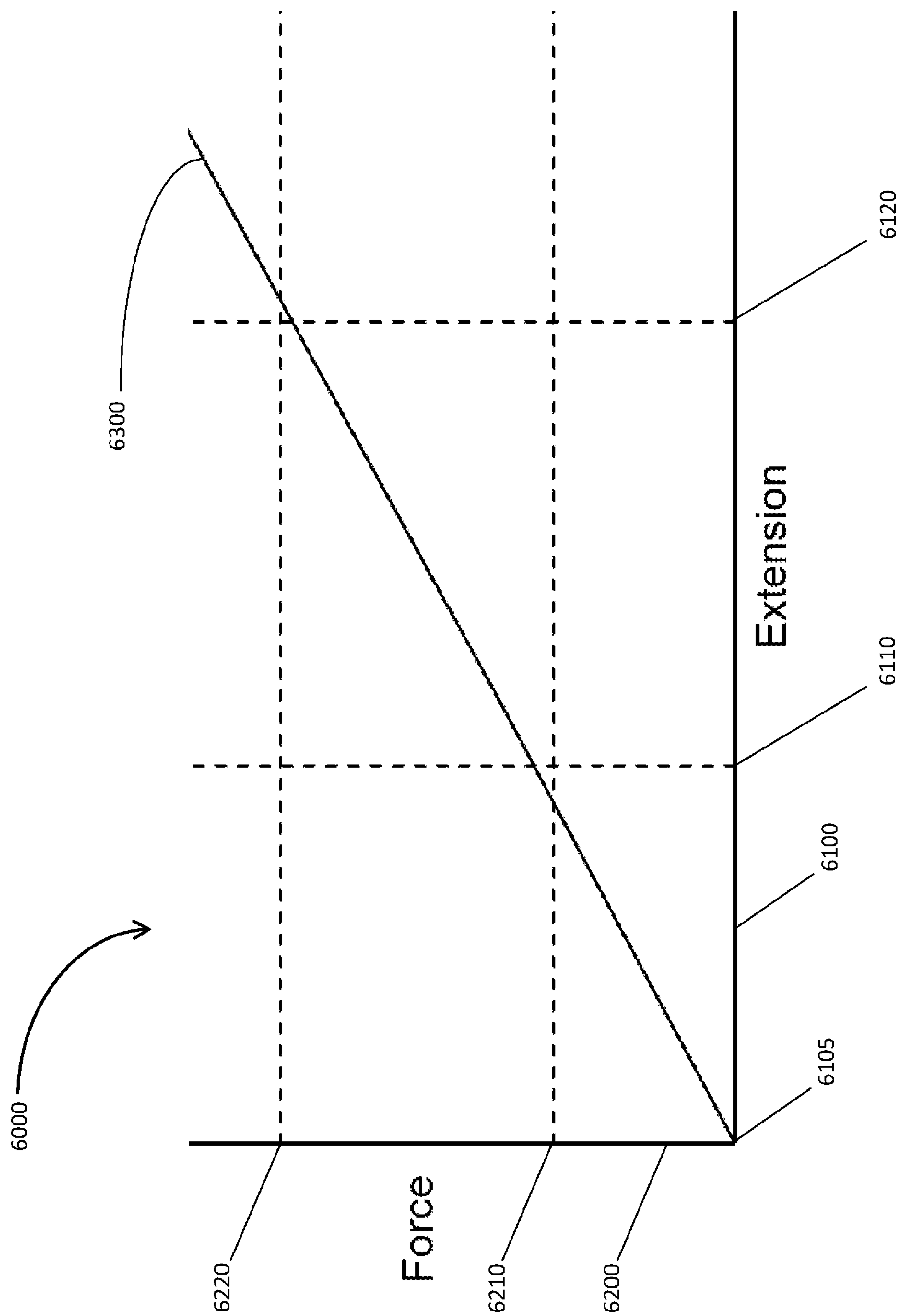


FIG. 3H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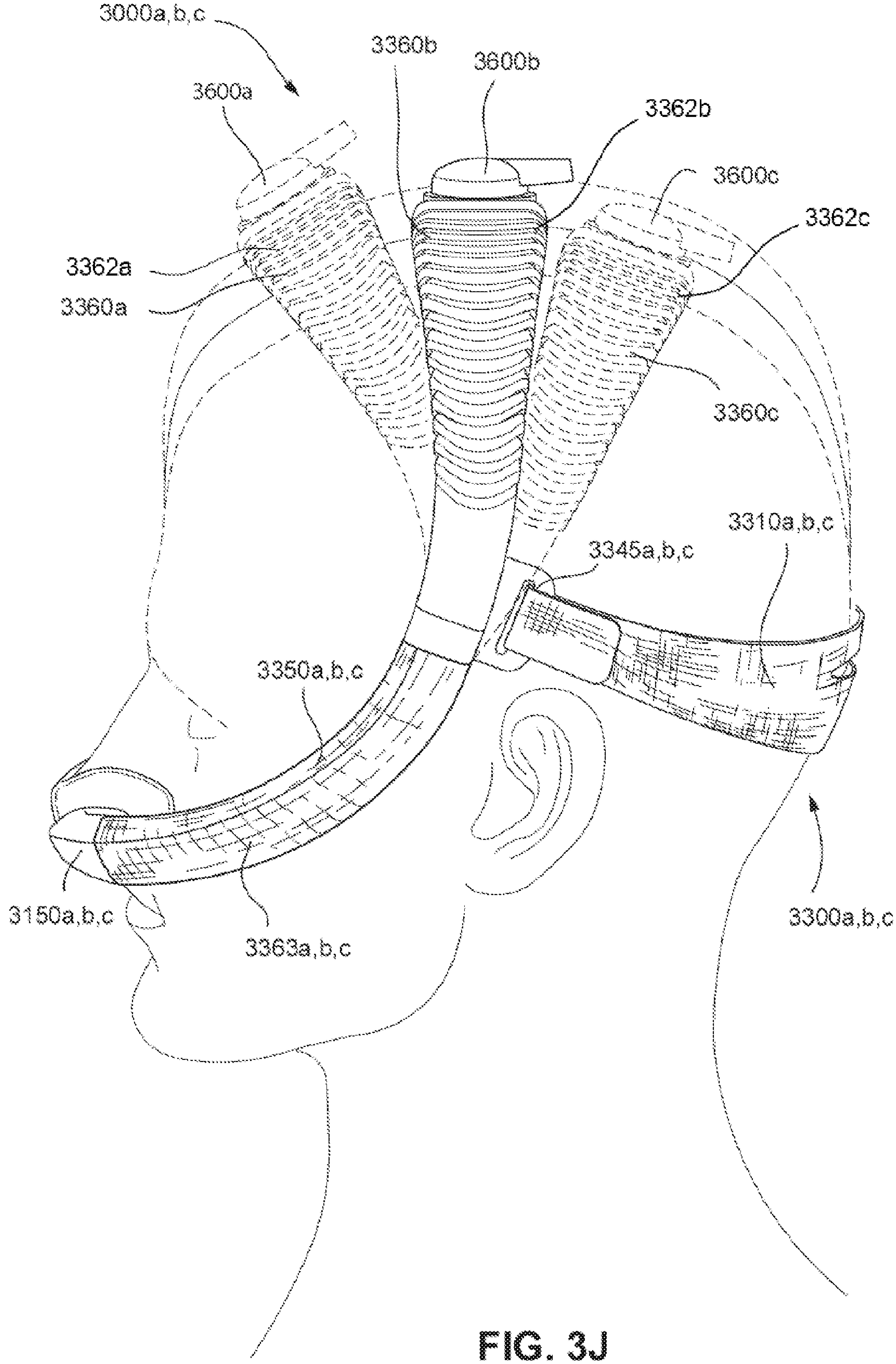
6300
6120
6110
6100
6105
Extension
Force
6220
6210
6200

FIG. 3I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3600b
3600a
3362b
3600c
3362c
3362a
3360a
3360c
3310a,b,c
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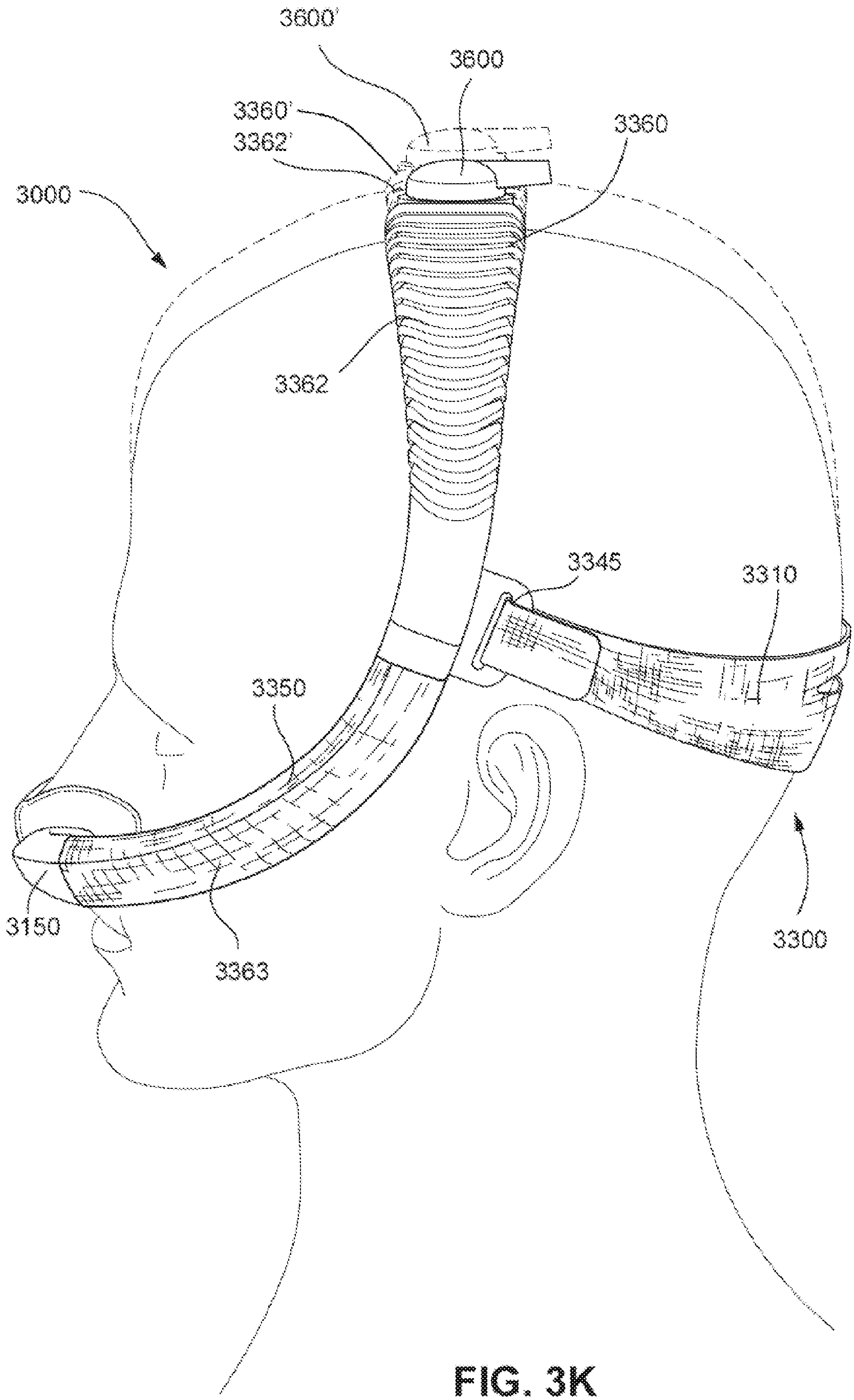
3150a,b,c
3363a,b,c
3300a,b,c

FIG. 3J


3600'
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3362'
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3000
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3345
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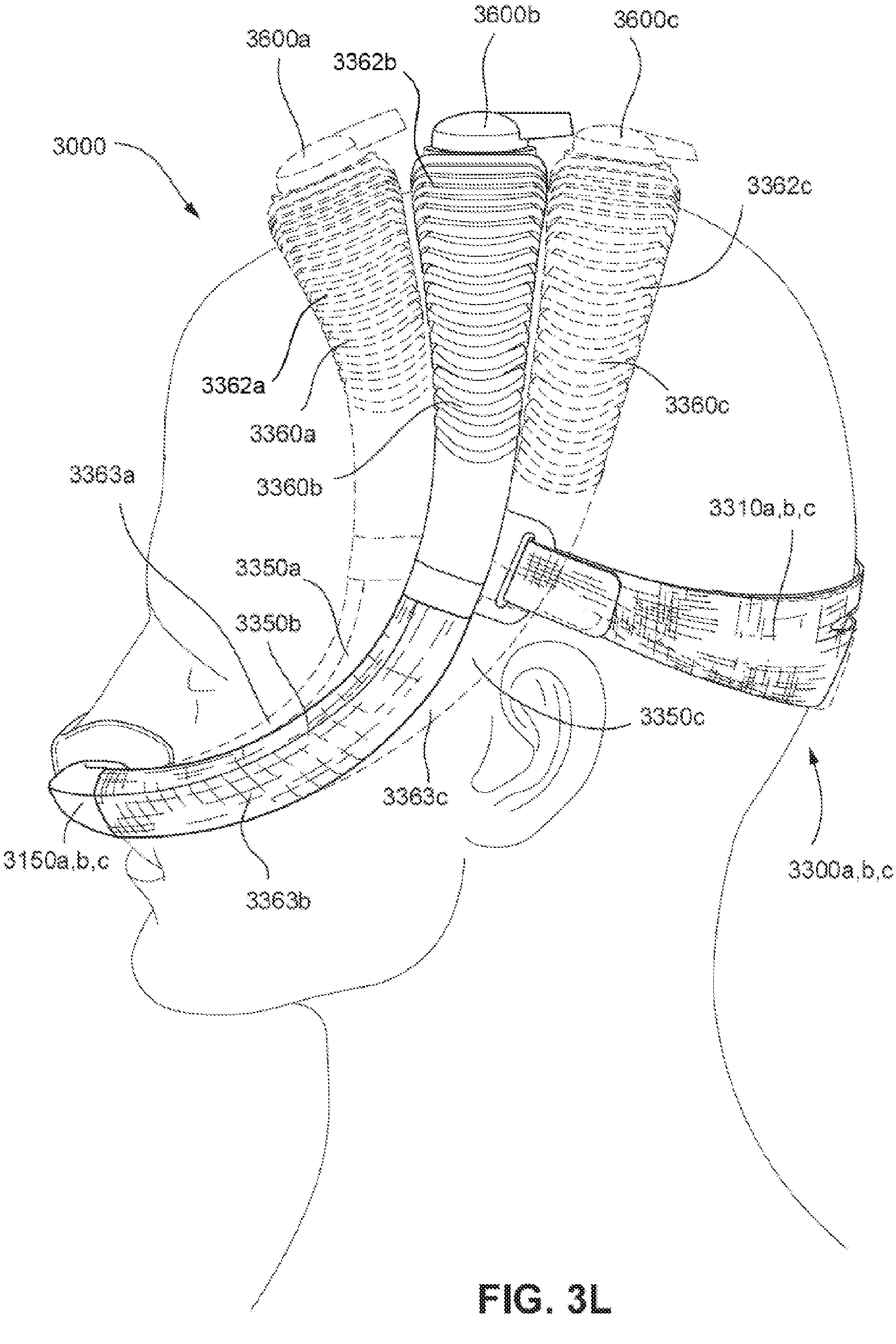
3150
3363
3300

FIG. 3K


3600a
3600b
3600c
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3362c
3362a
3360c
3360a
3360b
3363a
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3350c
3363c
3150a,b,c
3363b
3300a,b,c

FIG. 3L

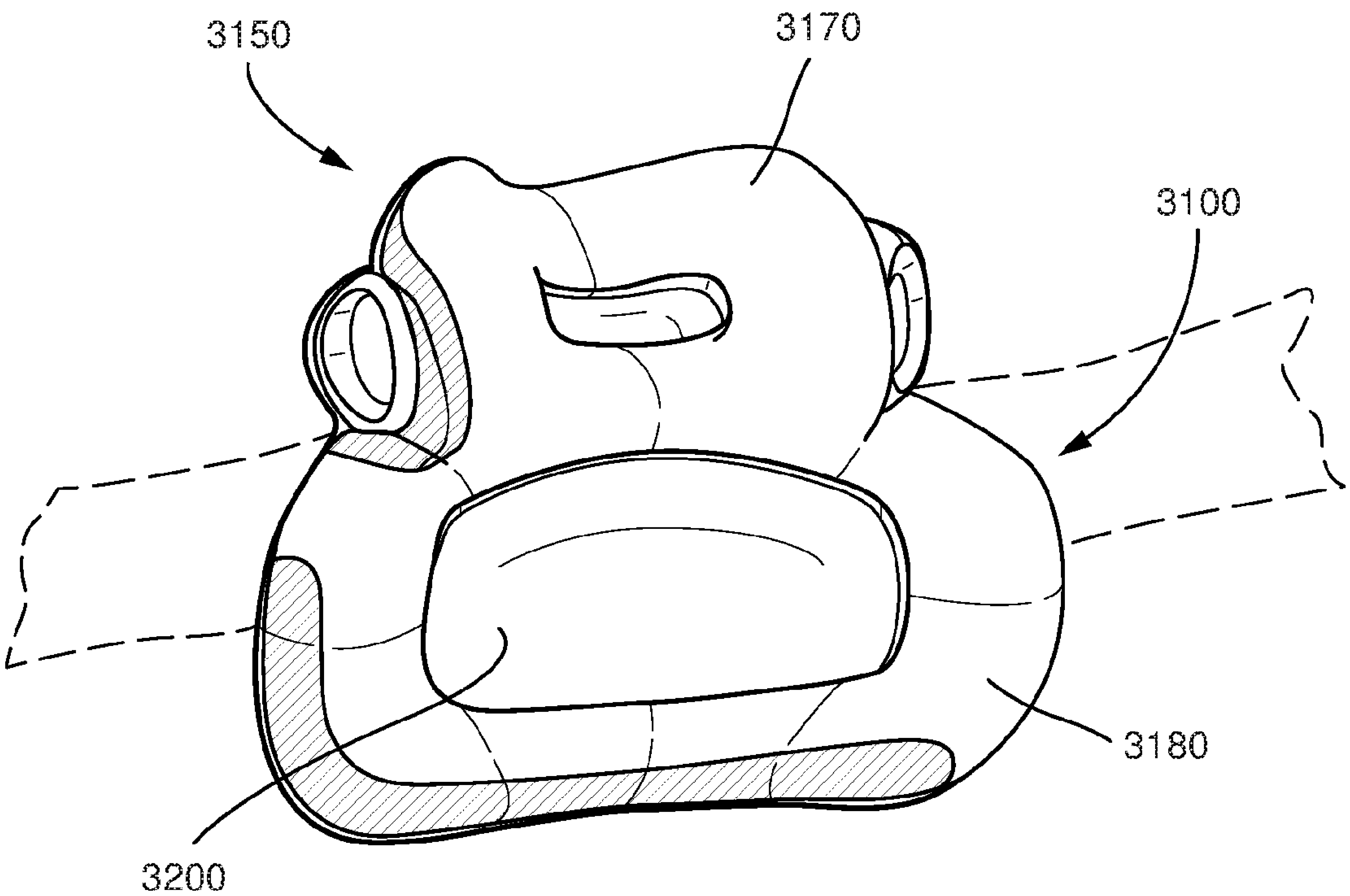

FIG. 4A

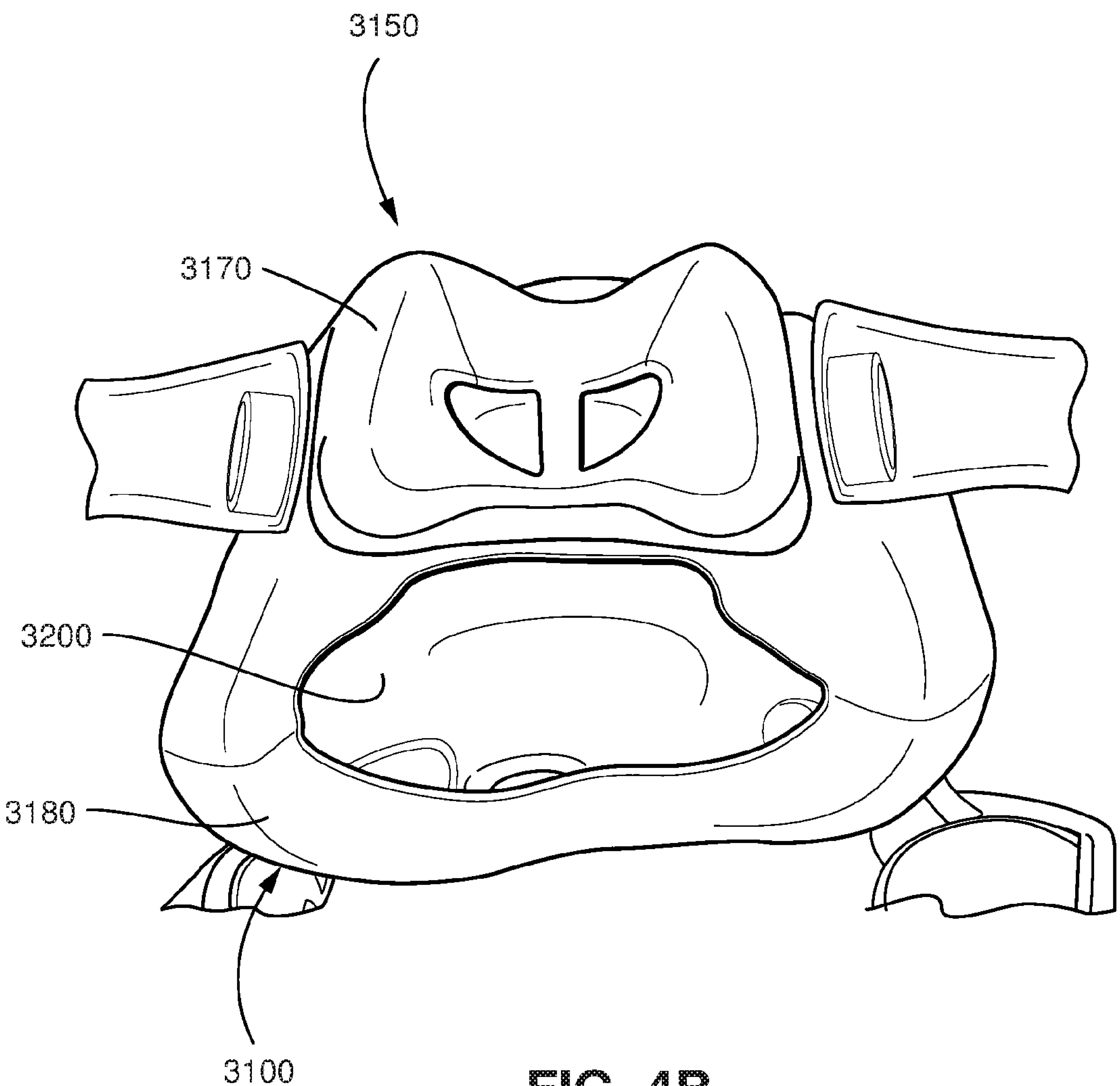

FIG. 4B

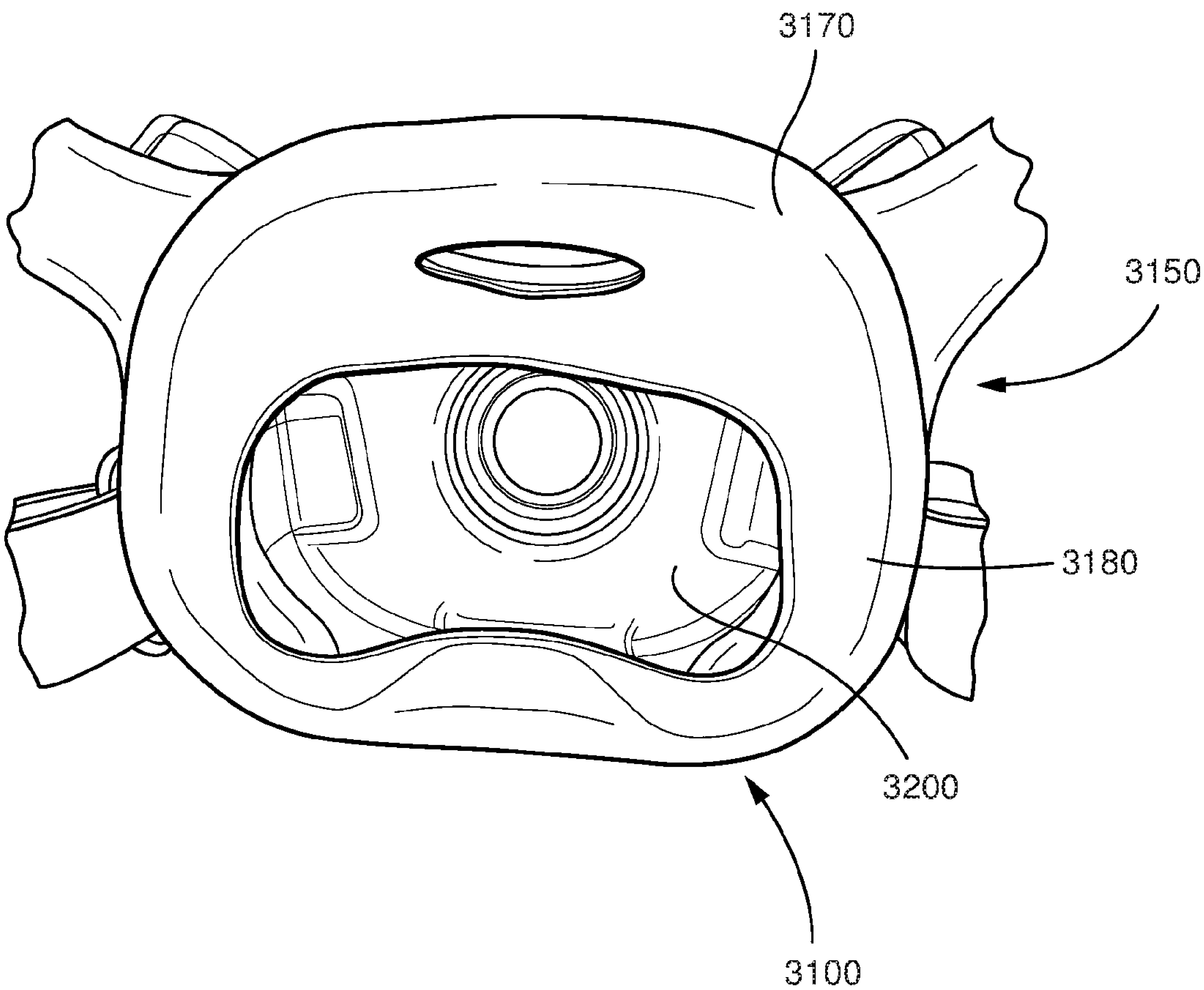

FIG. 4C

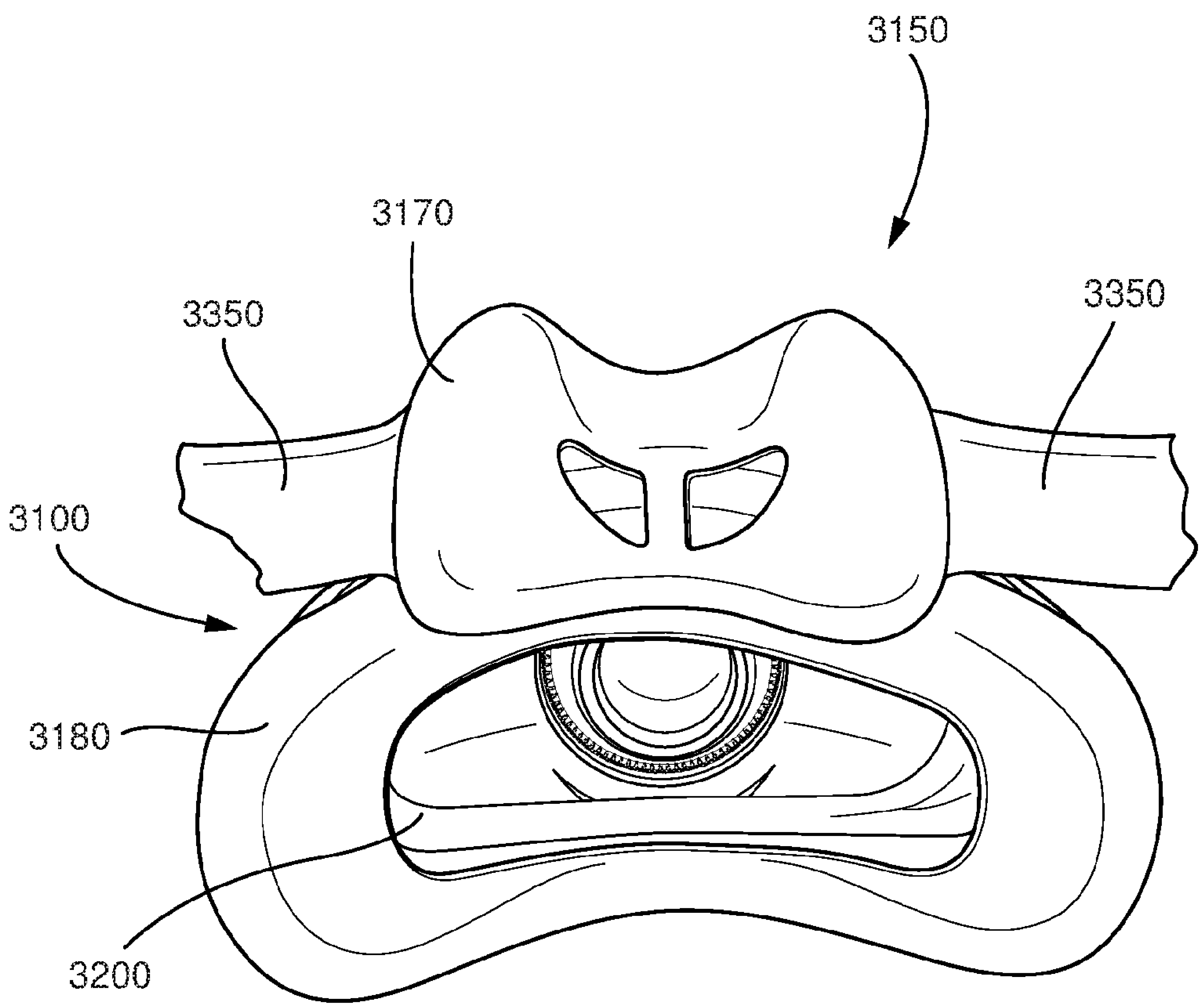

FIG. 4D

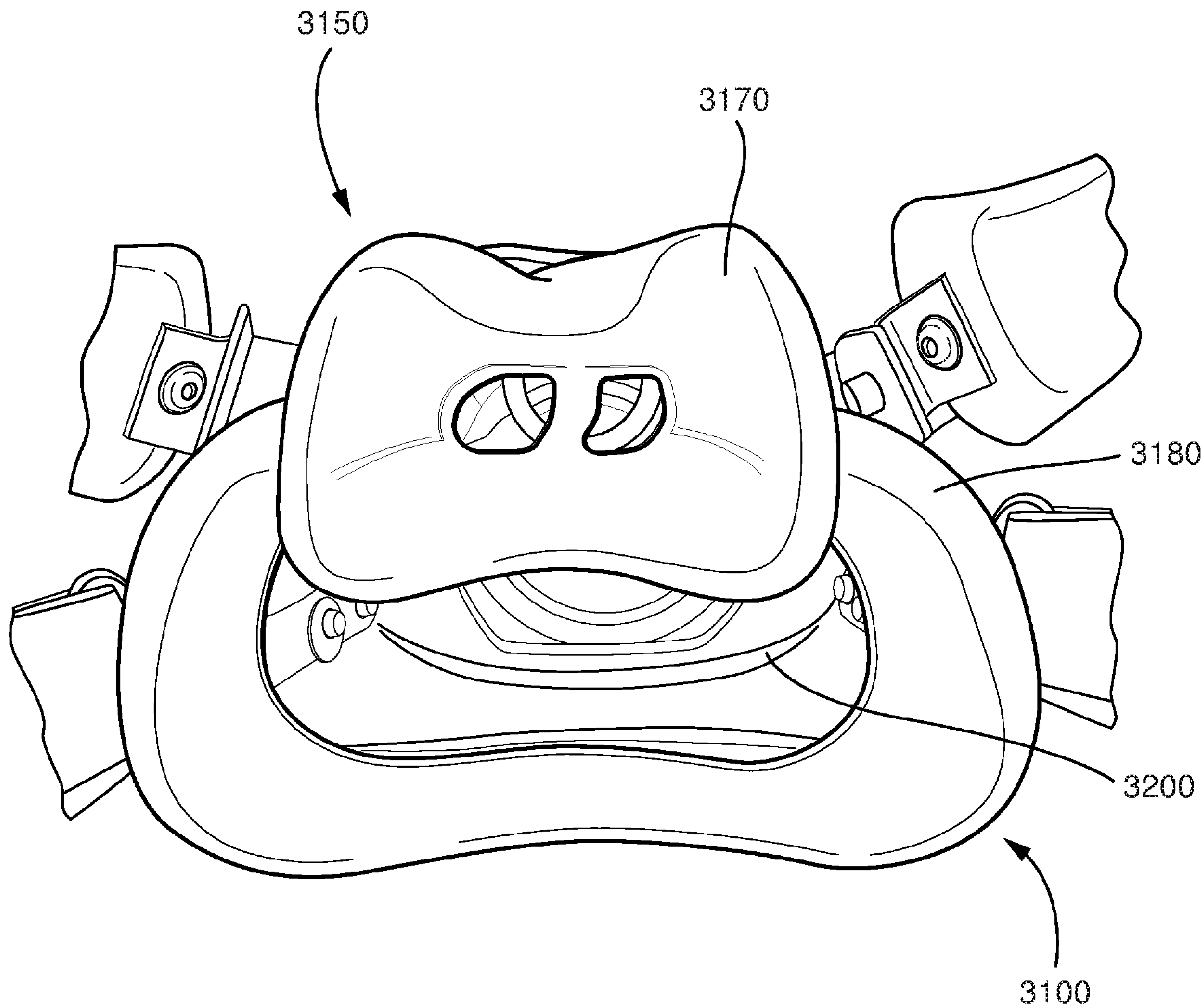

FIG. 4E

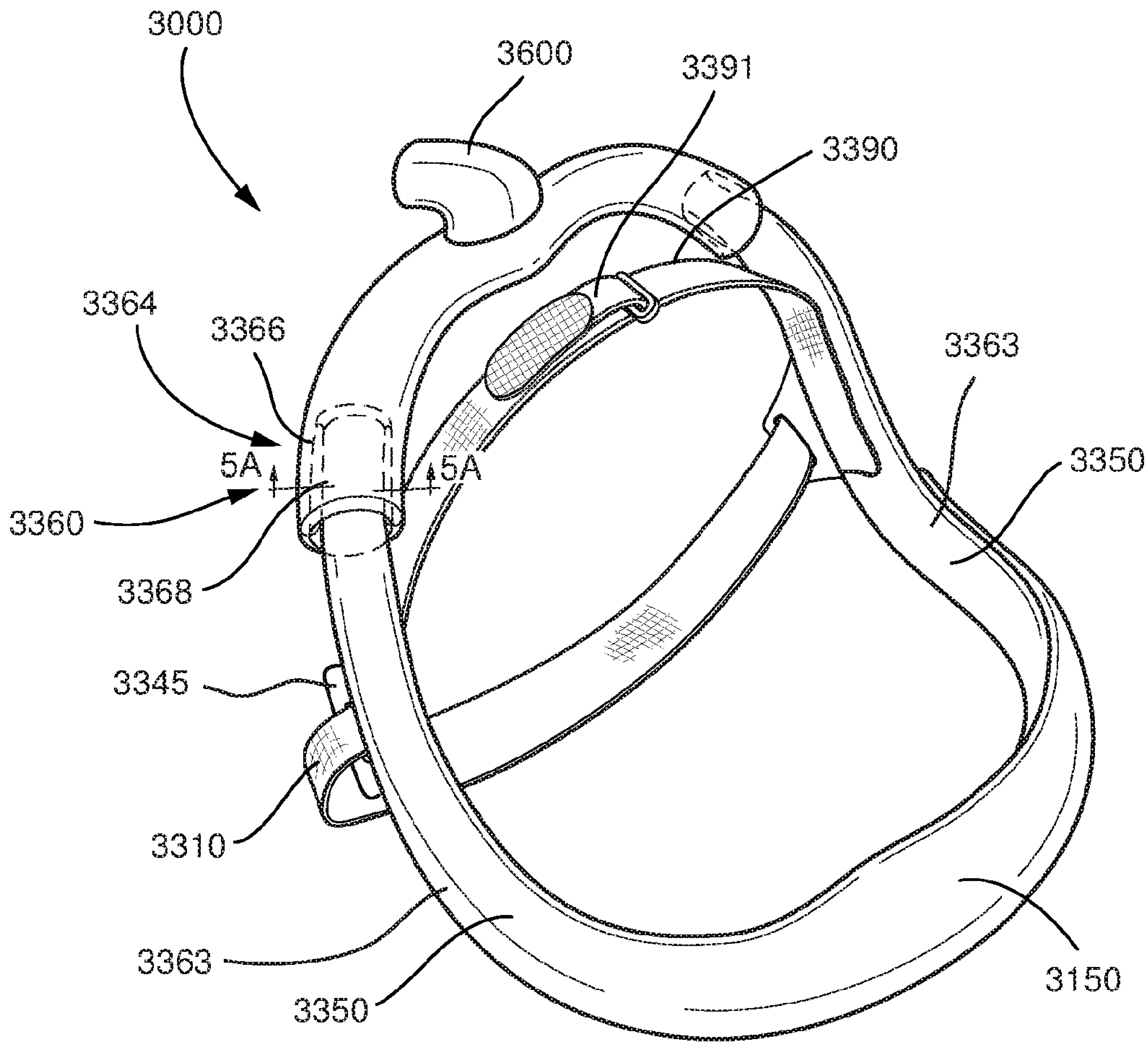

FIG. 5

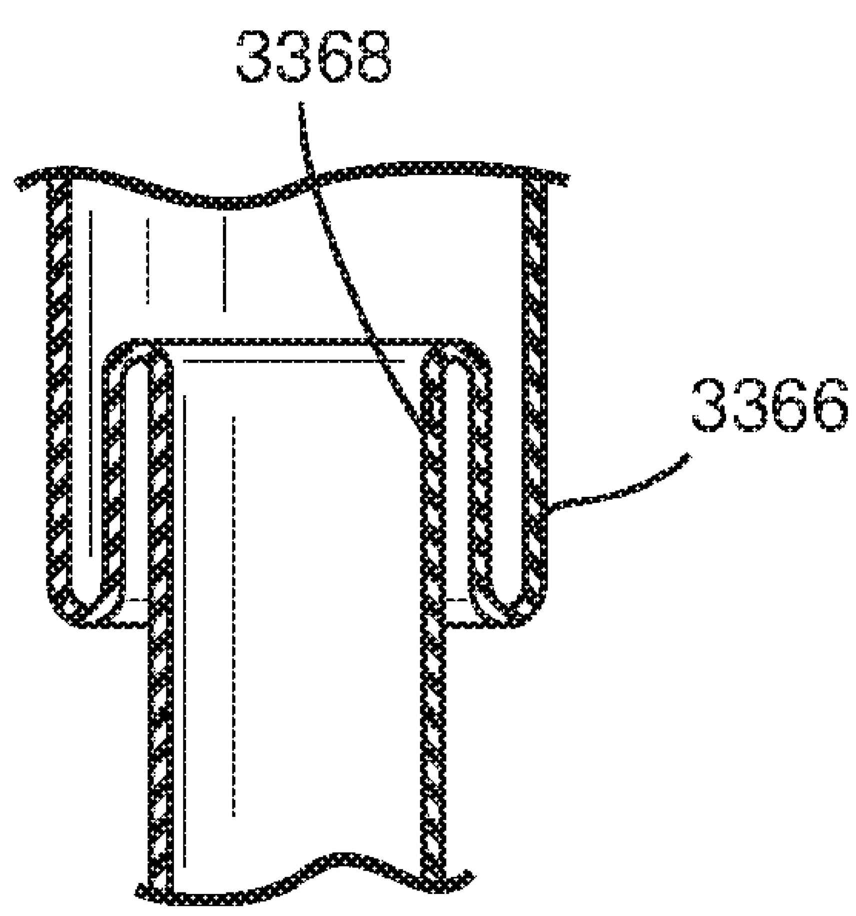

FIG. 5A

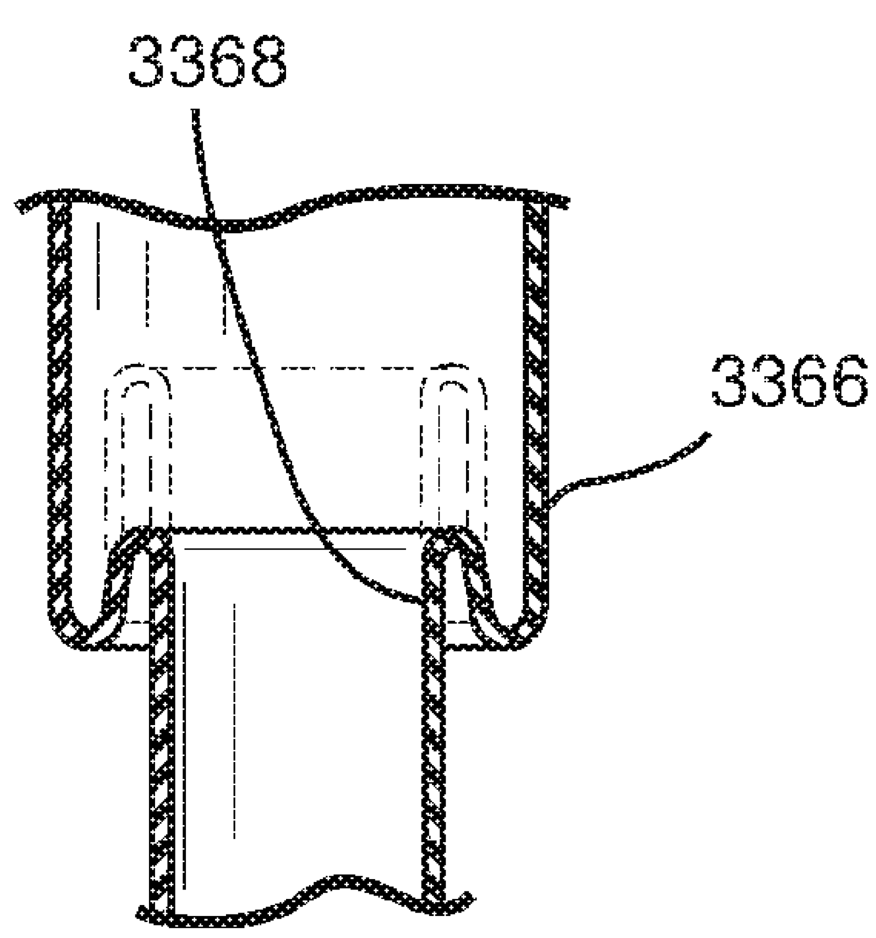

FIG. 5B

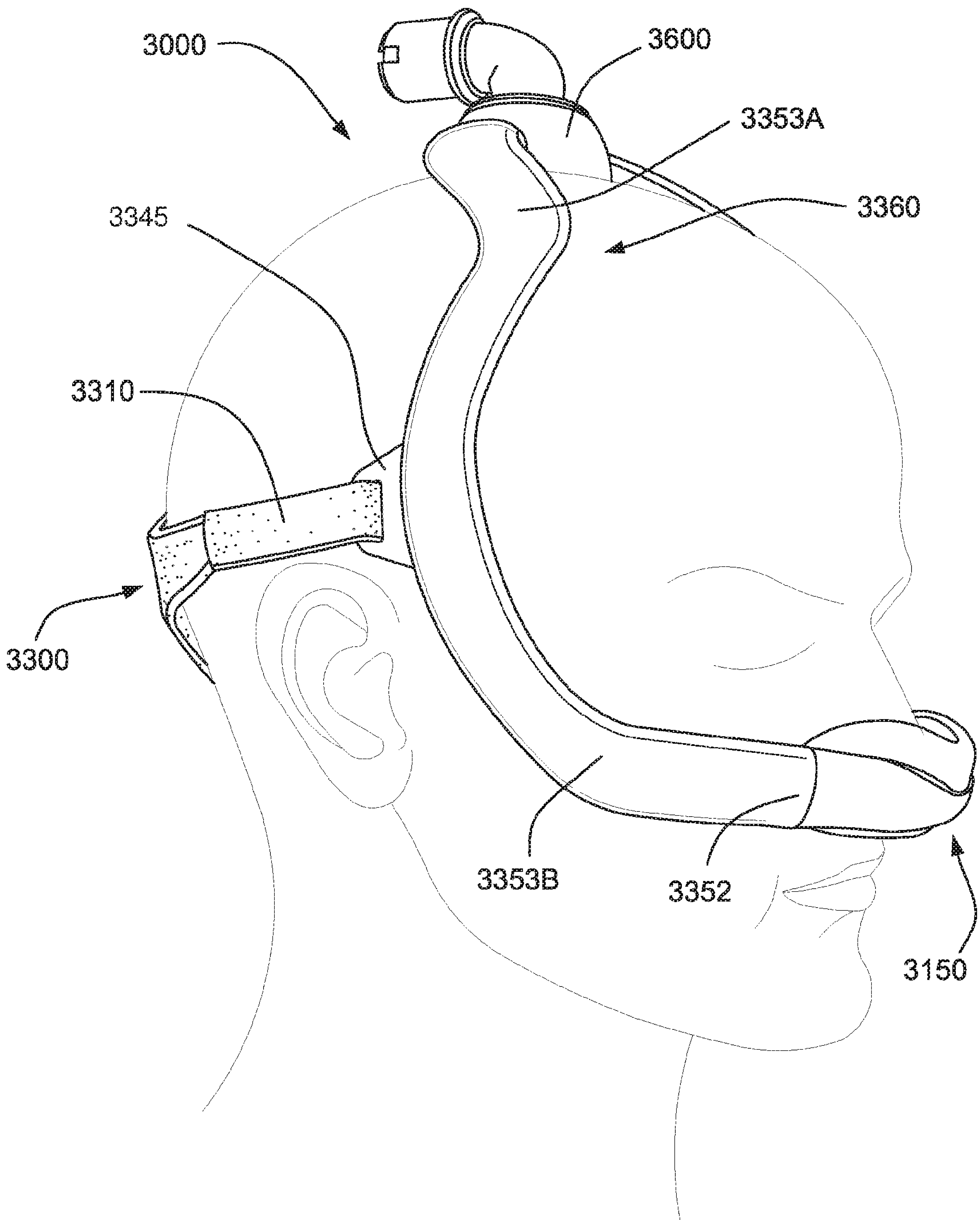

FIG. 6

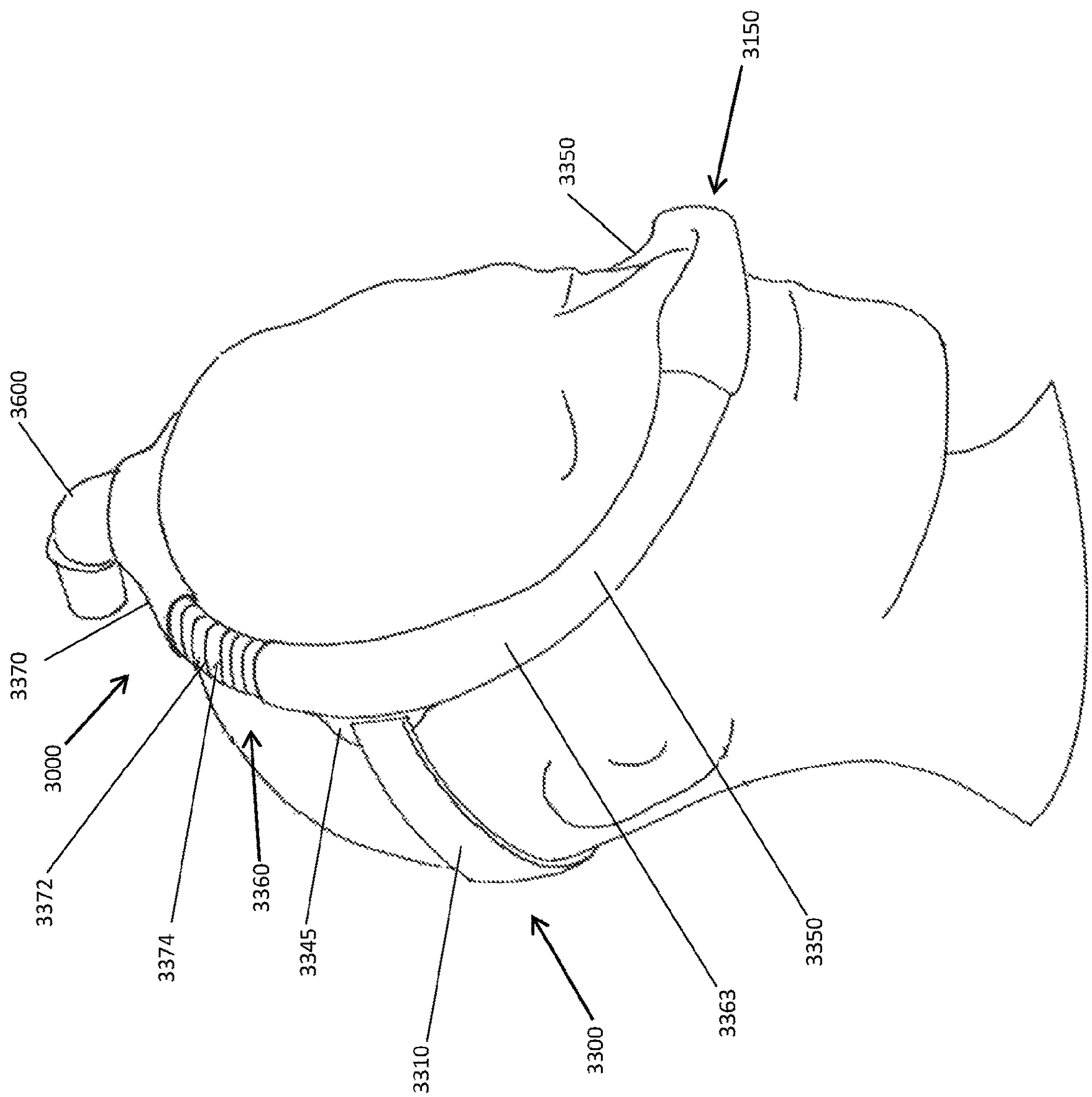
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FIG. 7A

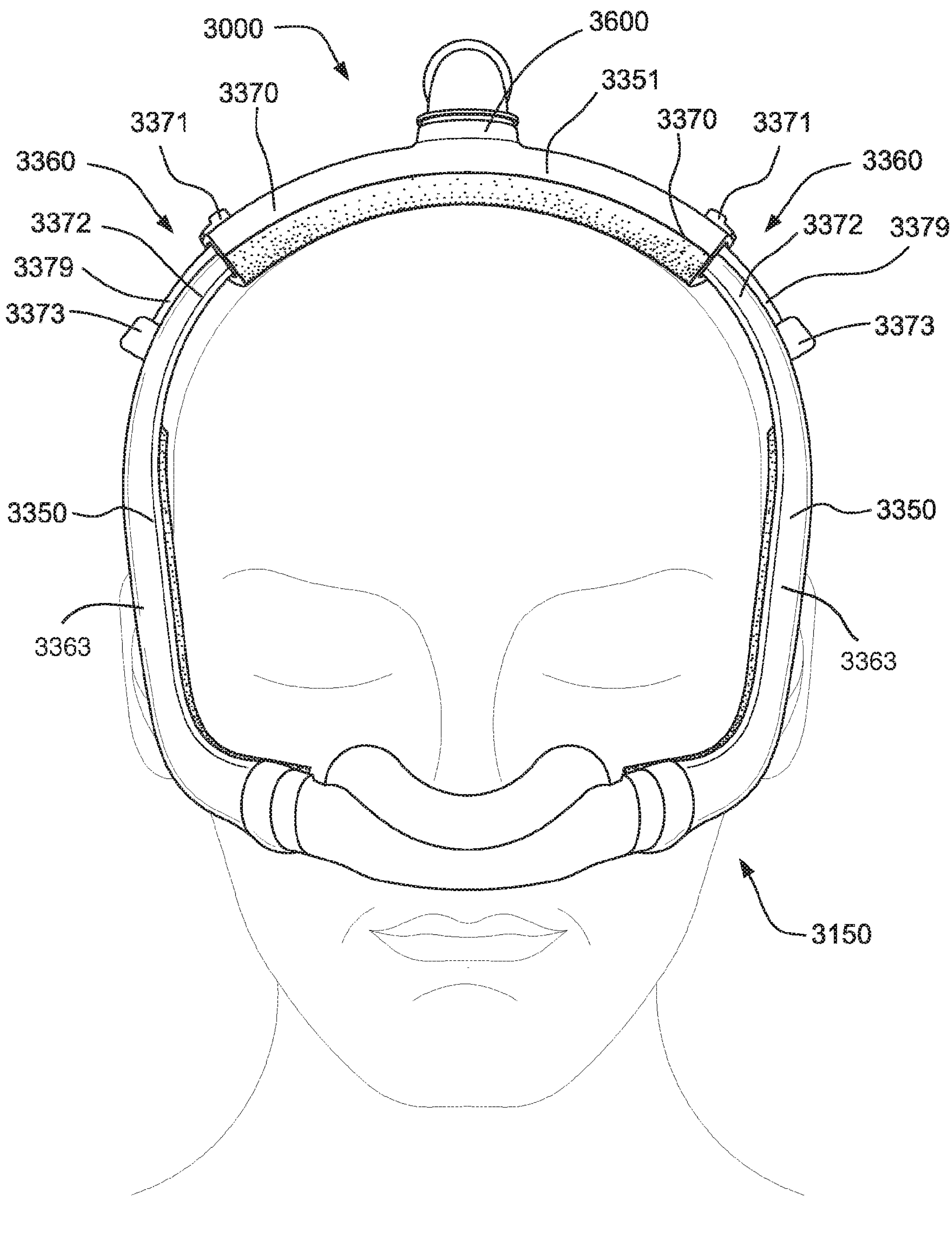
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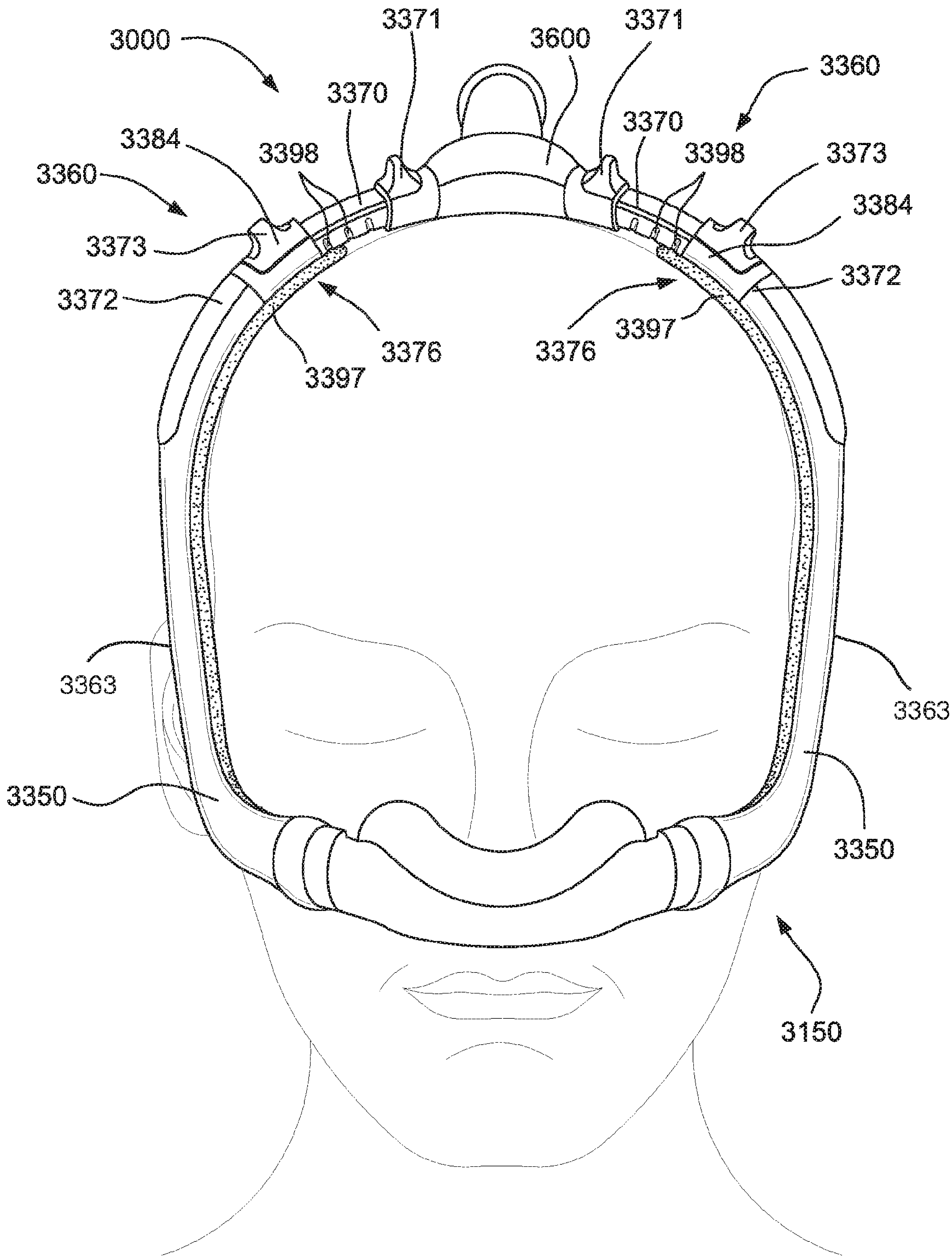
FIG. 7B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3376
3397
3397
3363
3363
3350
3350
3150

FIG. 7C

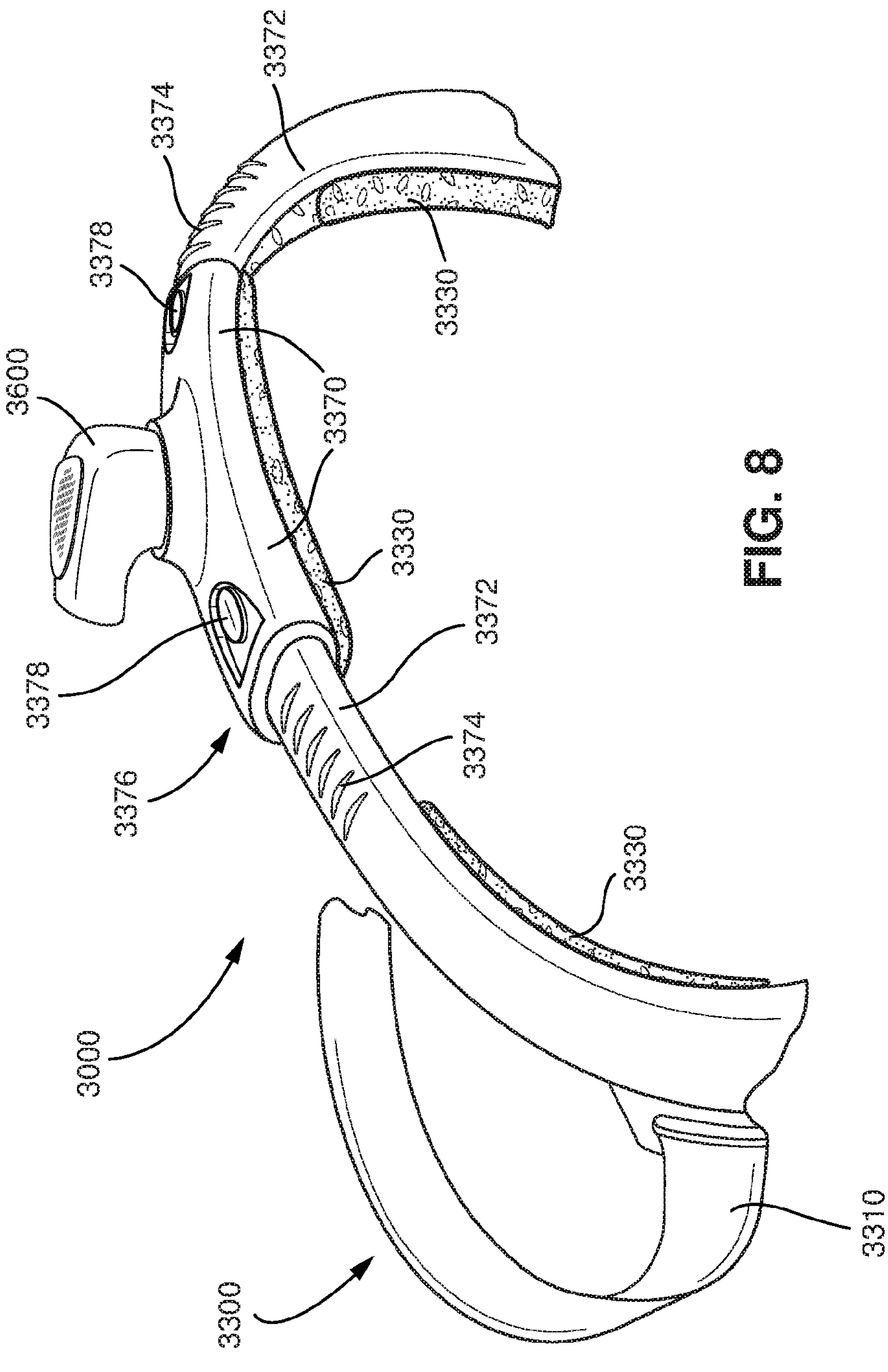
3372
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FIG. 8

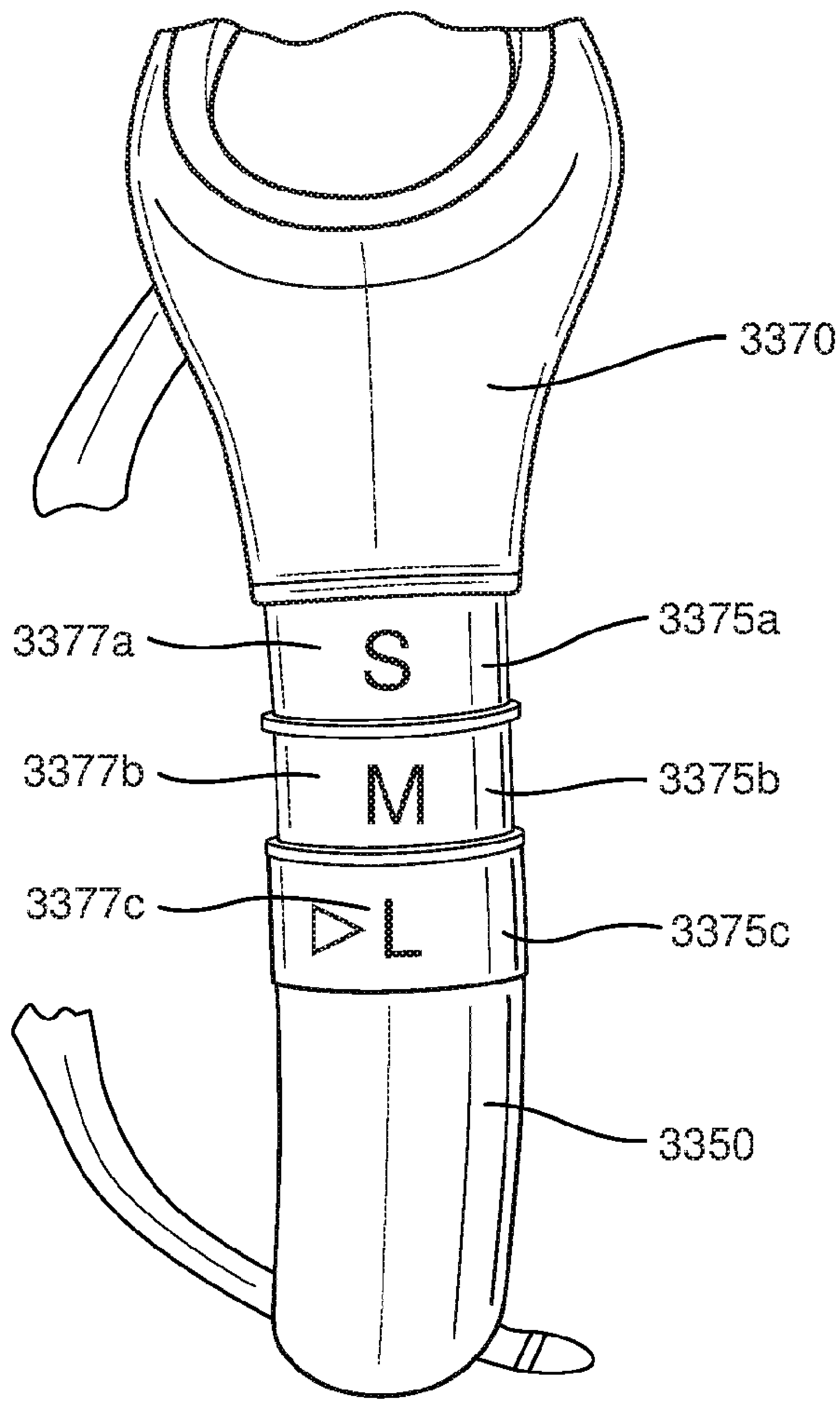

FIG. 9

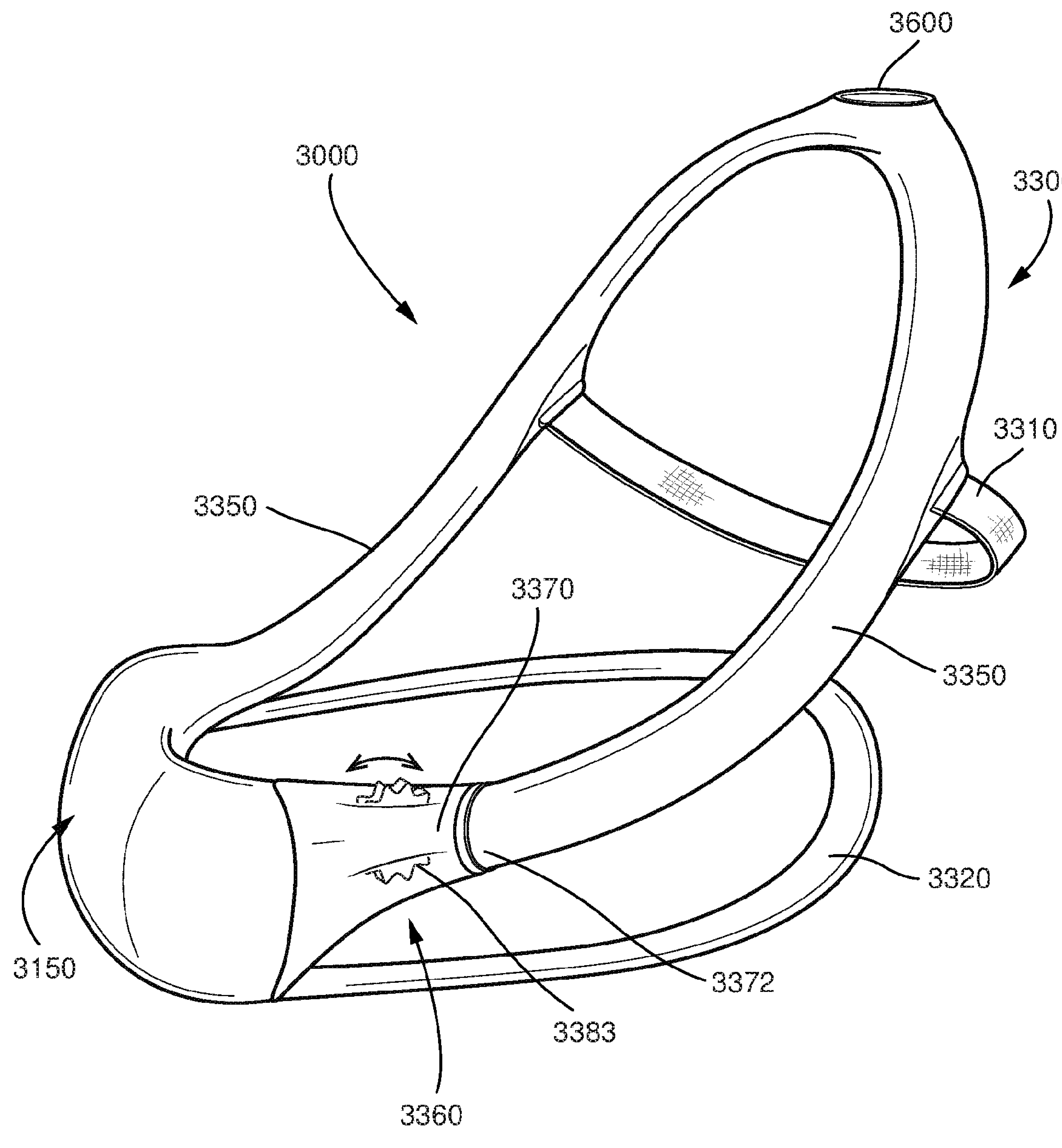

FIG. 10A

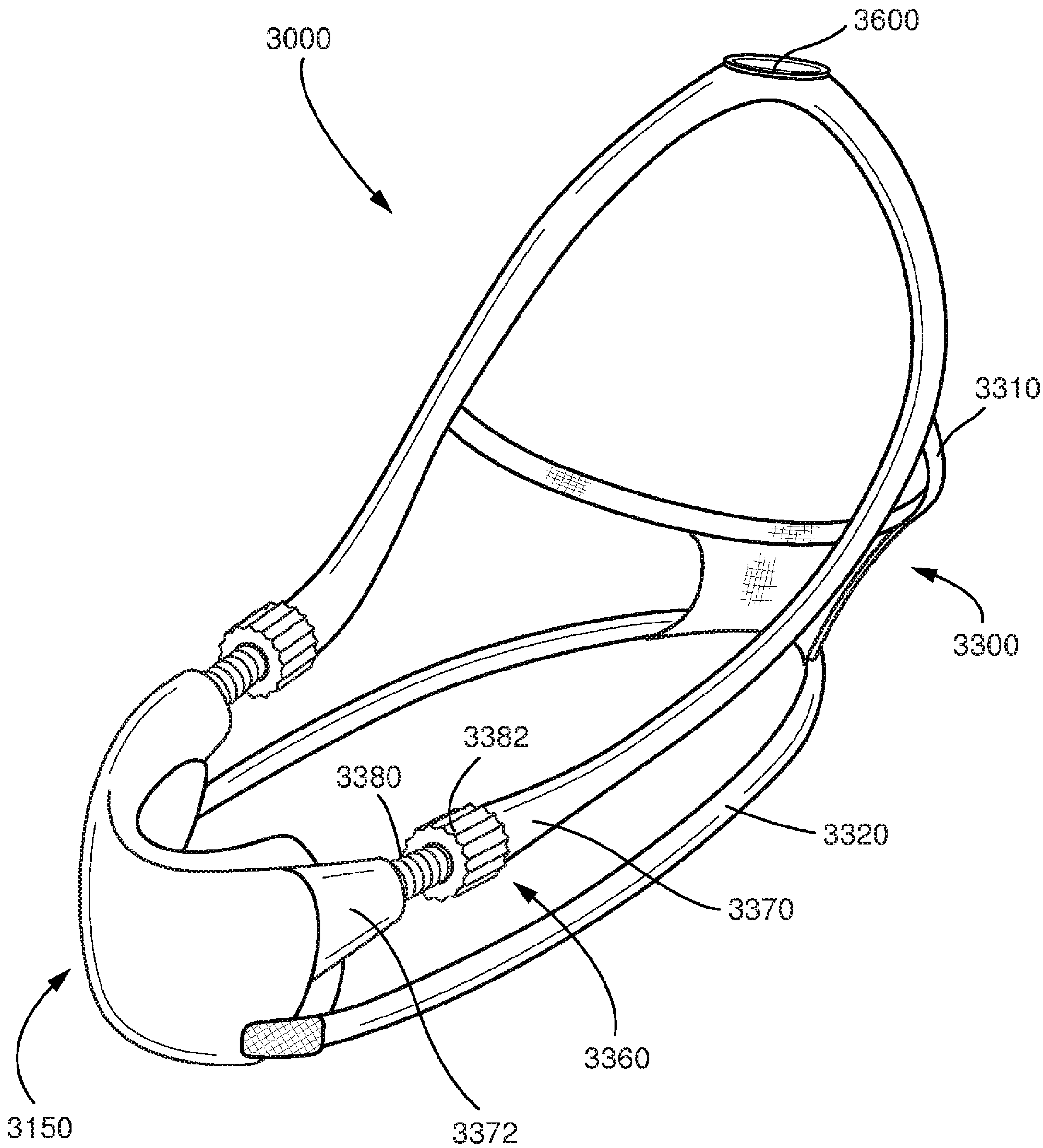

FIG. 10B

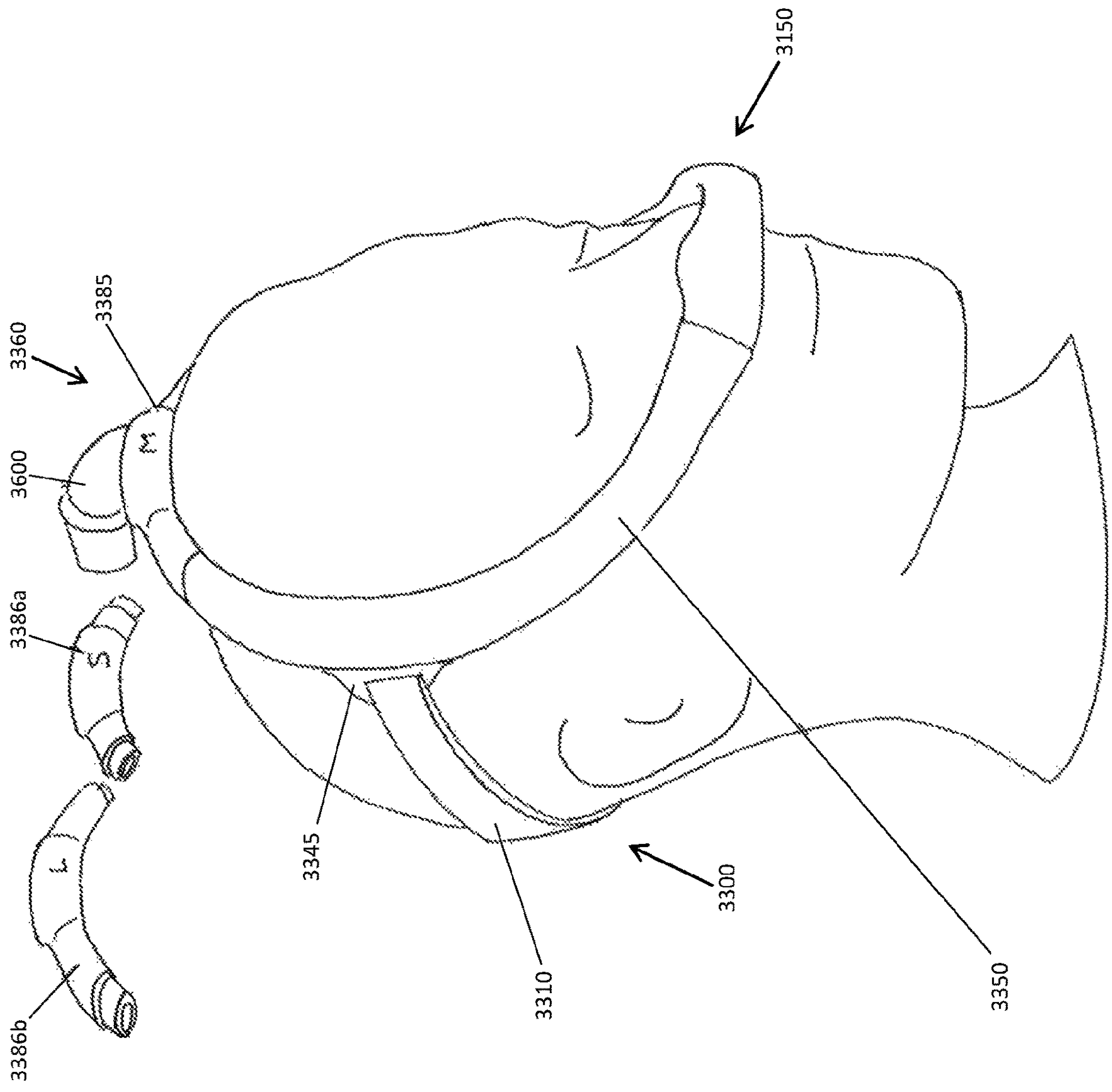

FIG. 11

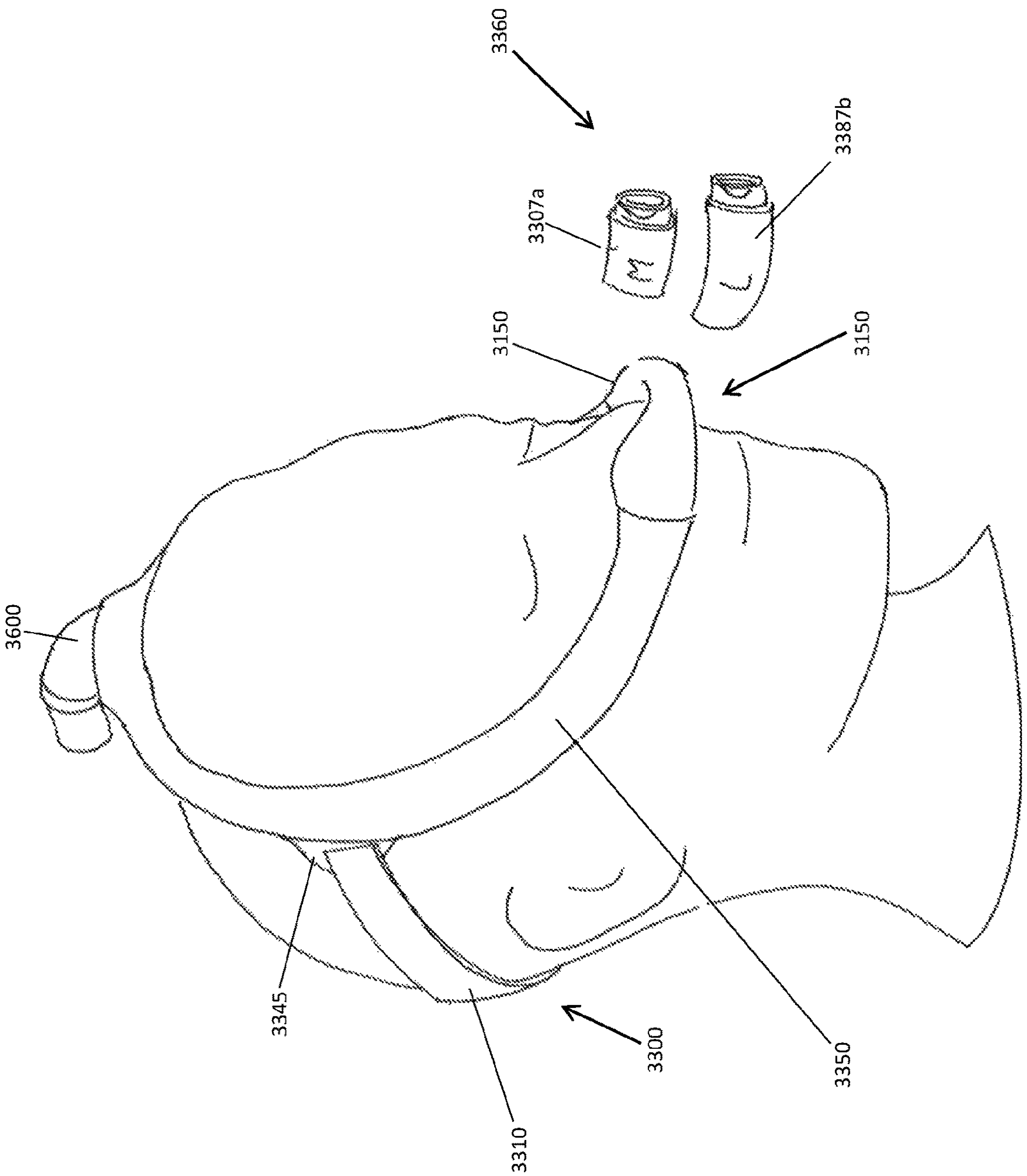

FIG. 12

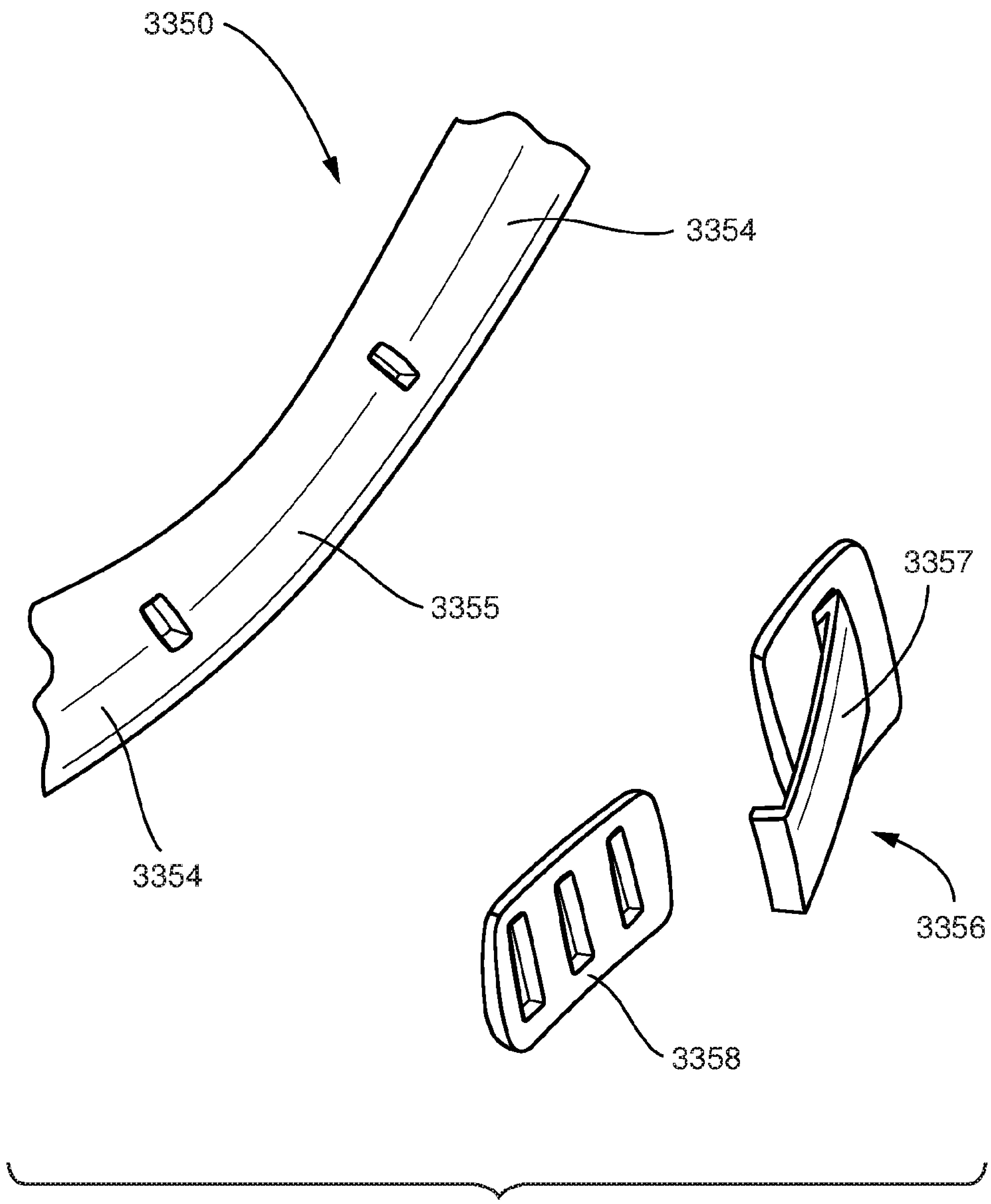

FIG. 13

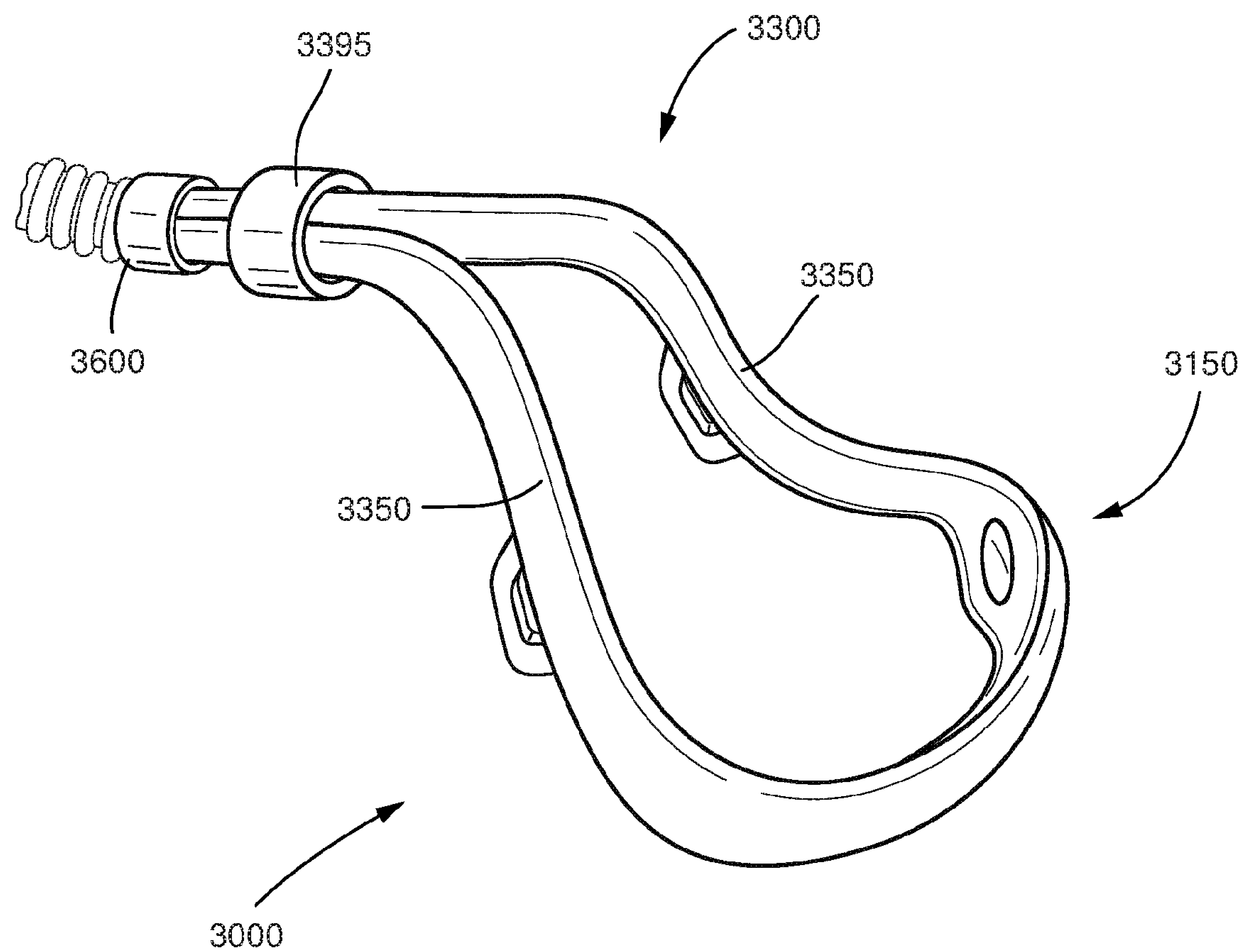

FIG. 14

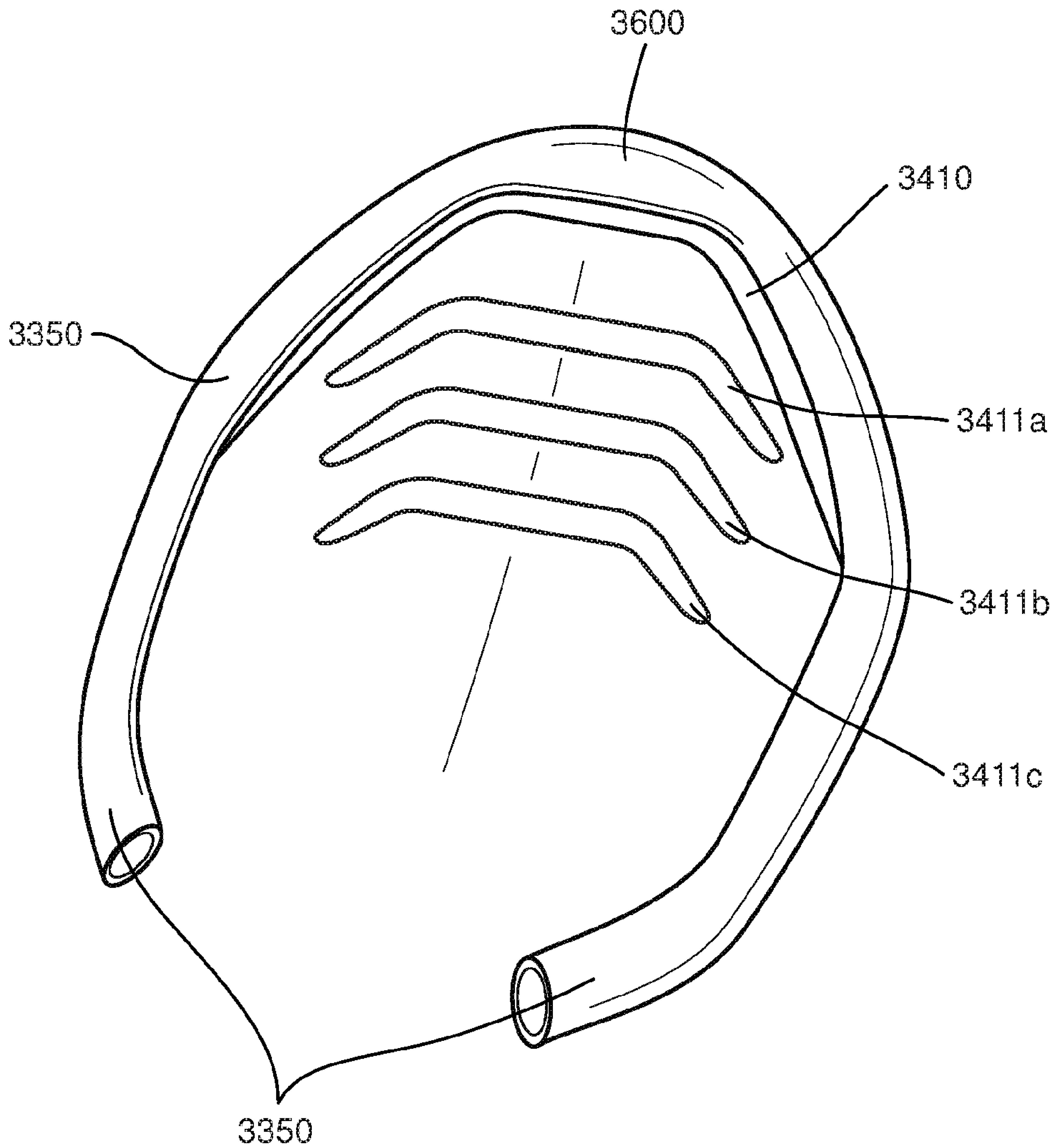

FIG. 15

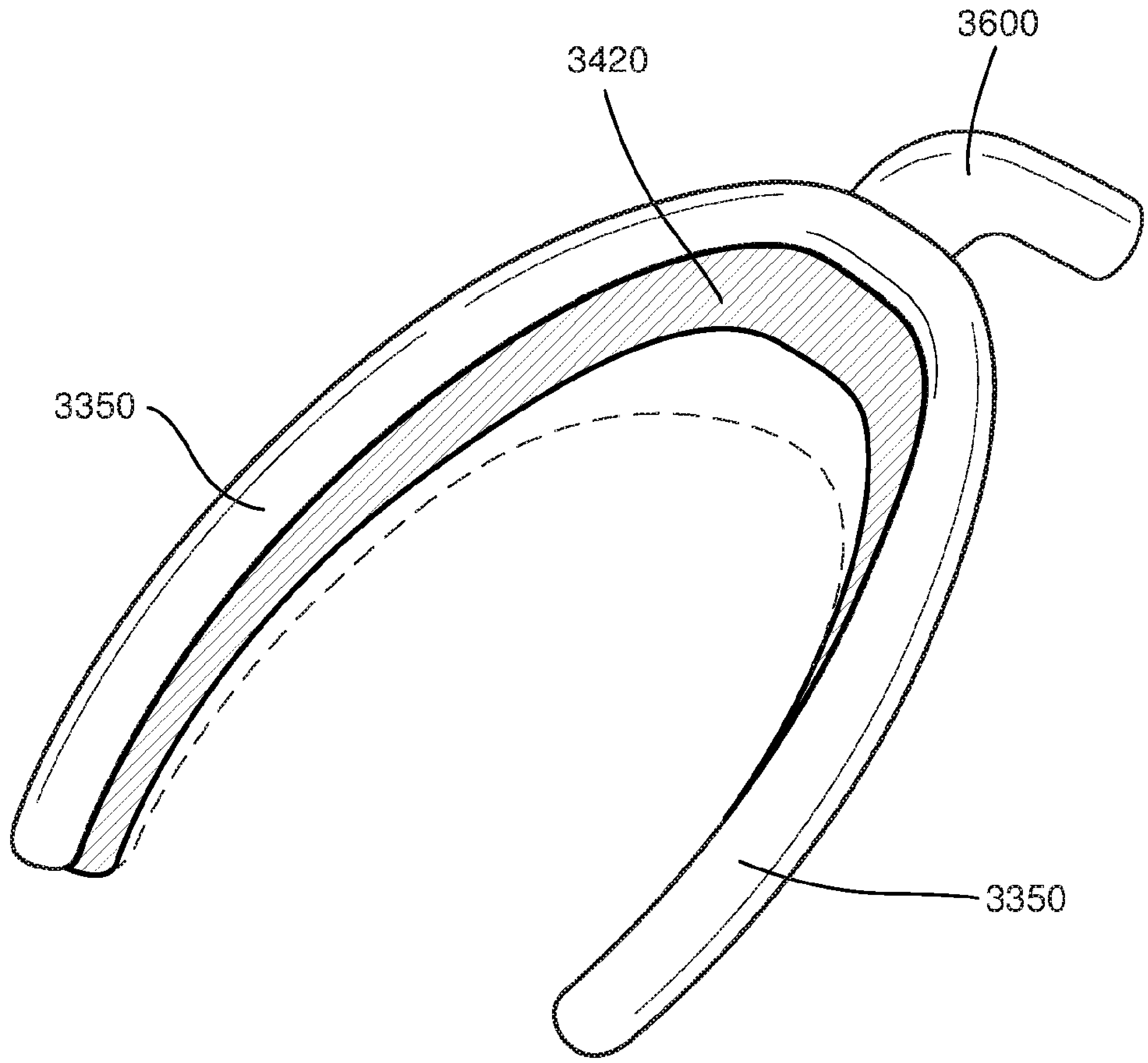

FIG. 16

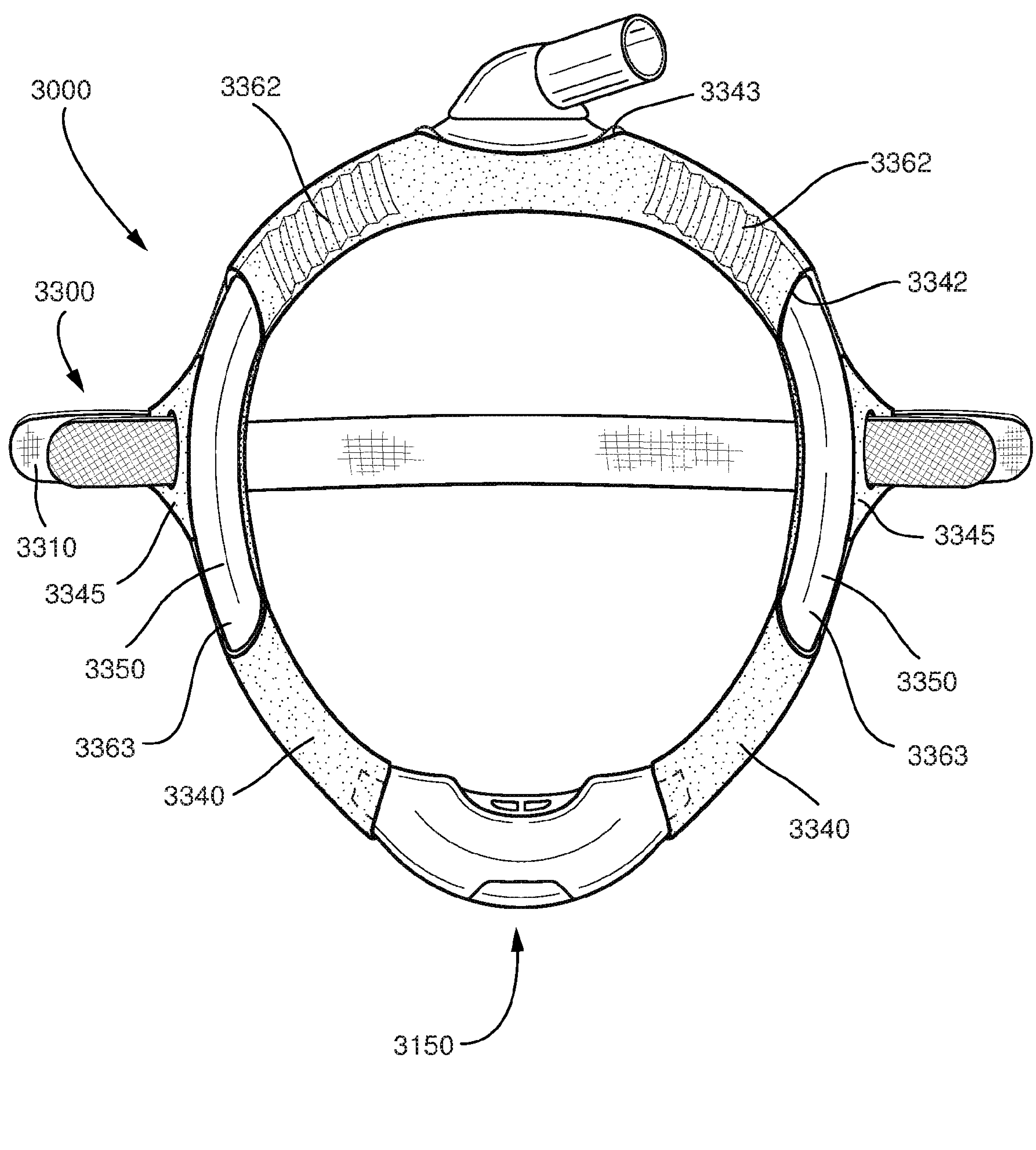
3000
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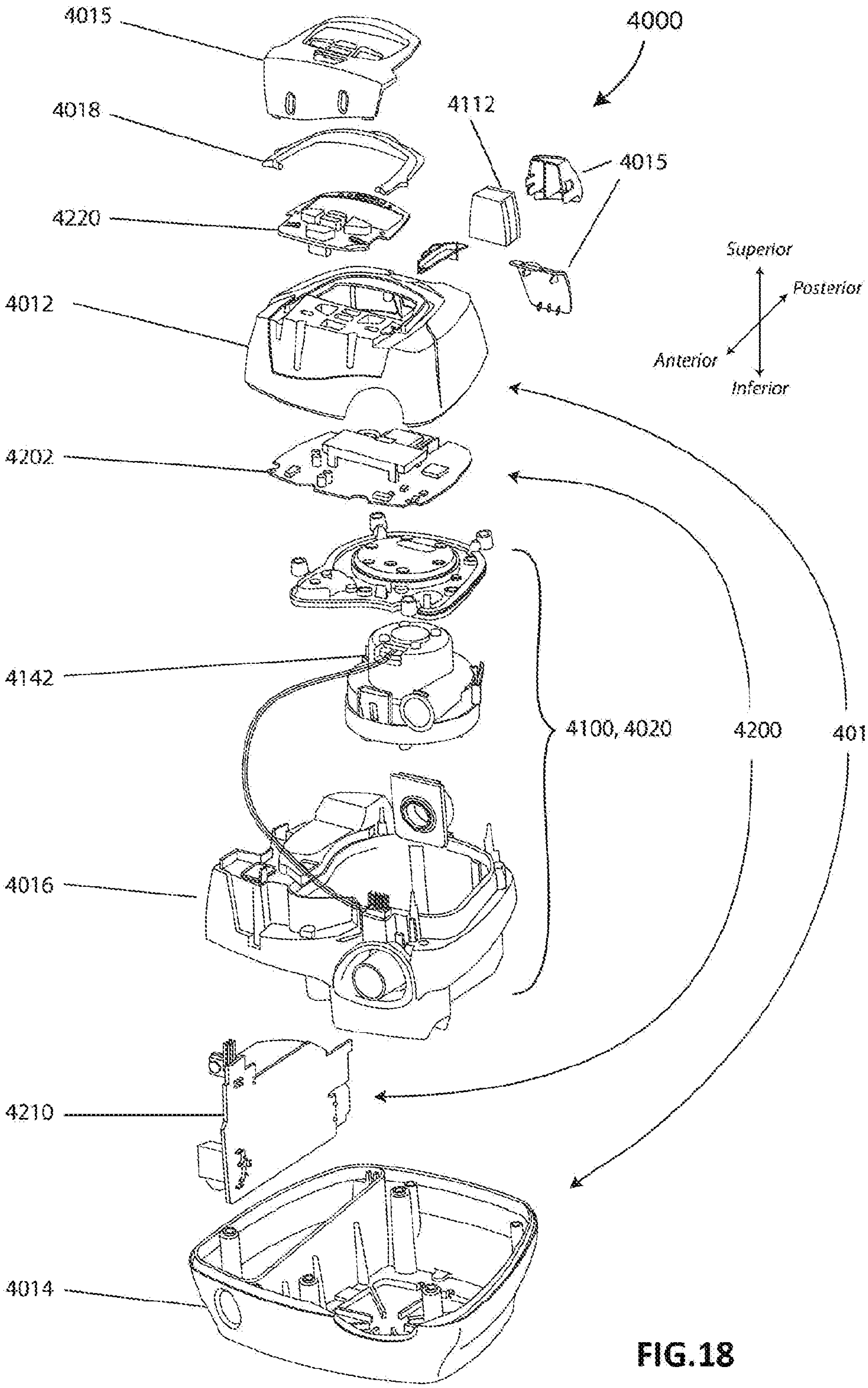
FIG. 17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4018
4112
4015
4220
Superior
Posterior
4012
Anterior
Inferior
4202
4142
4100, 4020
4200
4010
4016
4210
4014

FIG.18

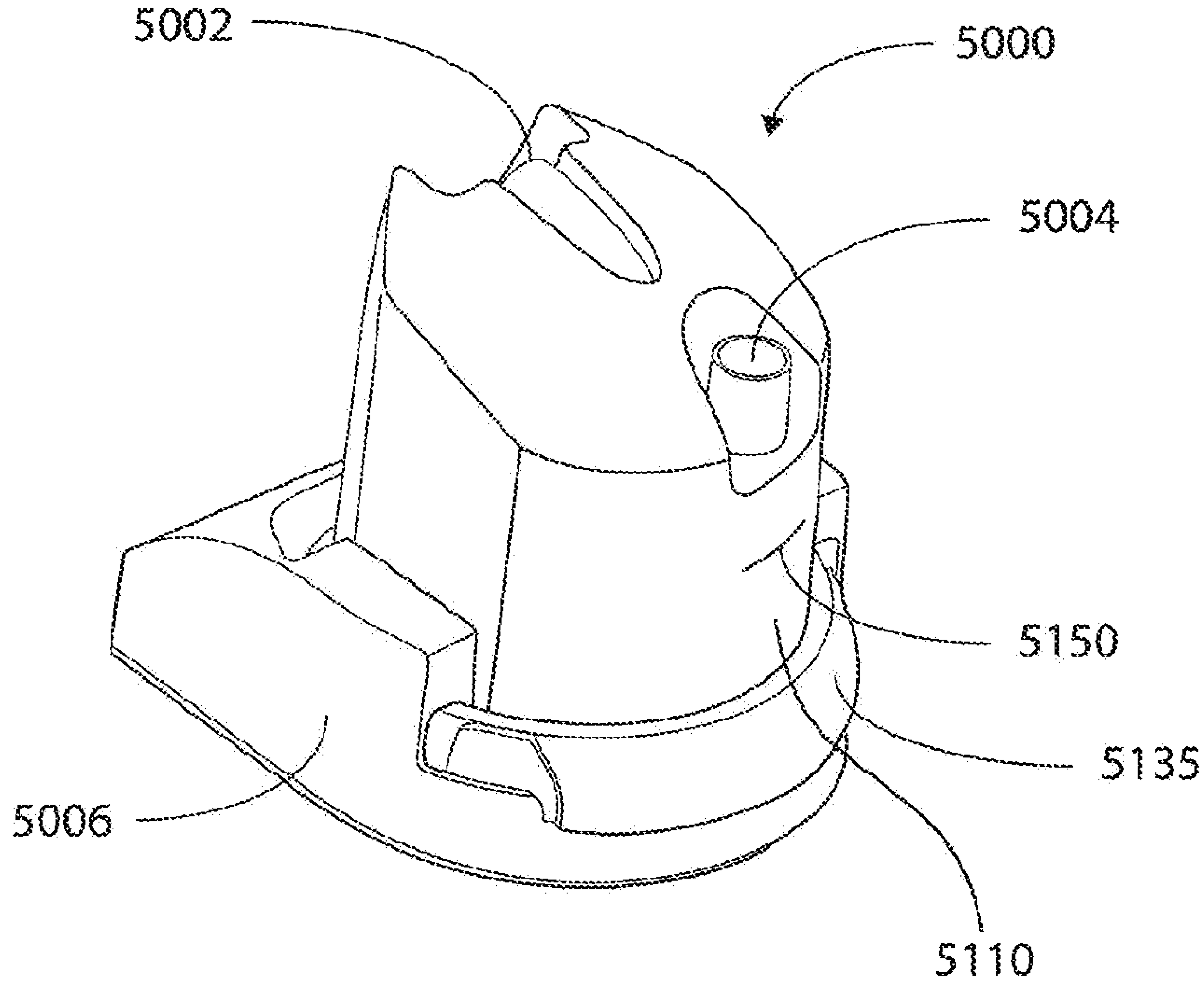

FIG. 19A

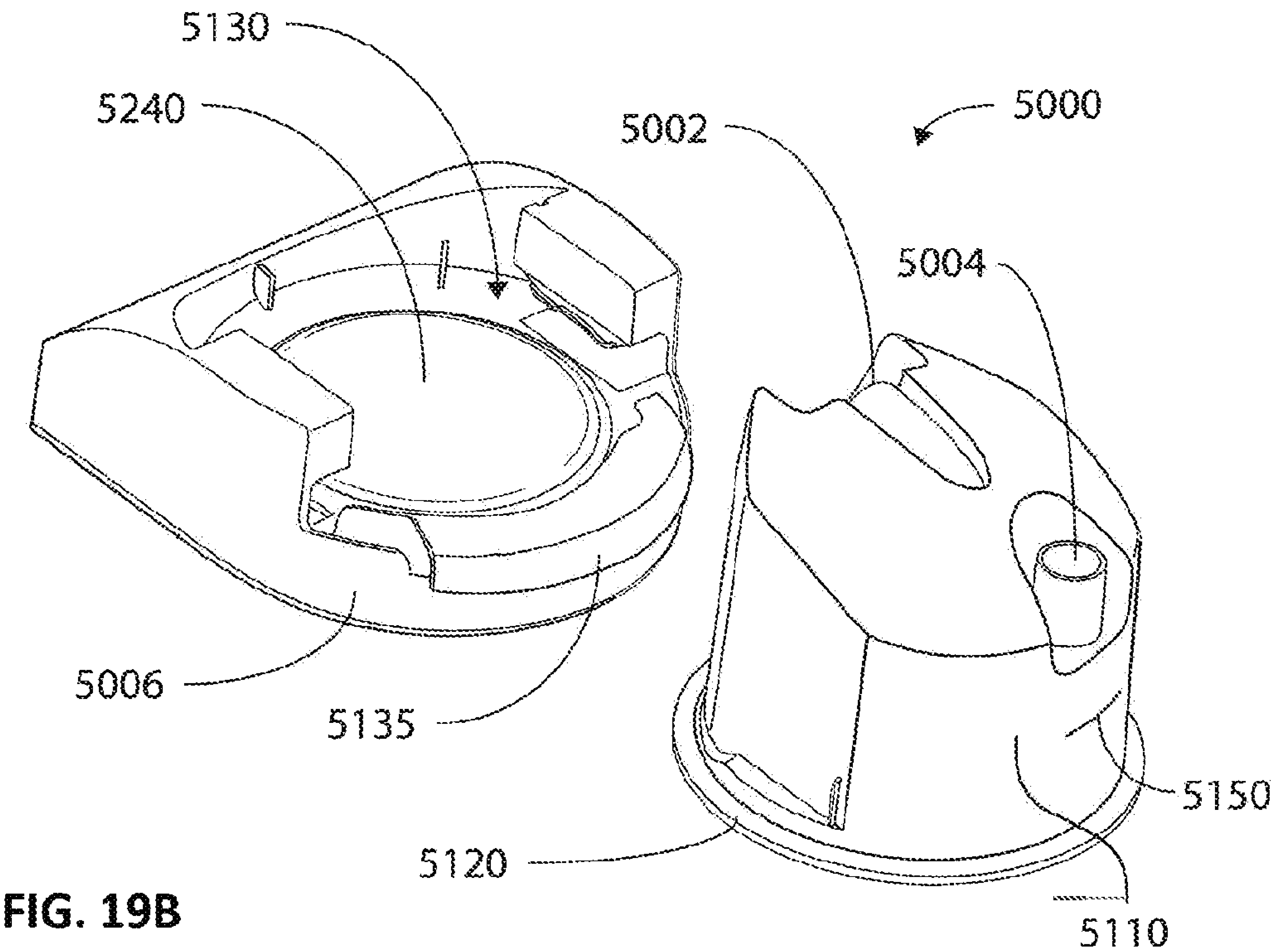

FIG. 19B

ADJUSTABLE HEADGEAR TUBING FOR A PATIENT INTERFACE

1 CROSS-REFERENCE TO RELATED APPLICATIONS

This application is the U.S. national phase of International Application No. PCT/AU2017/050050 filed Jan. 23, 2017, which designated the U.S. and claims priority to PCT/AU2017/050044 filed Jan. 20, 2017, AU Patent Application No. 2016901163 filed Mar. 30, 2016, and claims the benefit of U.S. Provisional Patent Application No. 62/281,322 filed Jan. 21, 2016, and U.S. Provisional Patent Application No. 62/330,371, filed May 2, 2016, the entire contents of each of which are incorporated herein by reference in their entirety.

2 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

3 THE NAMES OF PARTIES TO A JOINT RESEARCH DEVELOPMENT

Not Applicable

4 SEQUENCE LISTING

Not Applicable

5 BACKGROUND OF THE TECHNOLOGY

5.1 Field of the Technology

The present technology relates to one or more of the detection, diagnosis, treatment, prevention and amelioration of respiratory-related disorders. The present technology also relates to medical devices or apparatus, and their use.

Certain forms of the present technology relate to patient interfaces used in the treatment of respiratory, prevention and amelioration of respiratory-related disorders.

5.2 Description of the Related Art

5.2.1 Human Respiratory System and its Disorders

The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The prime function of the lung is gas exchange, allowing oxygen to move from the air into the venous blood and carbon dioxide to move out. The trachea divides into right and left main bronchi, which further divide eventually into terminal bronchioles. The bronchi make up the conducting airways, and do not take part in gas exchange. Further divisions of the airways lead to the respiratory bronchioles, and eventually to the alveoli. The alveolated region of the lung is where the gas exchange takes place, and is referred to as the respiratory zone. See "*Respiratory Physiology*", by John B. West, Lippincott Williams & Wilkins, 9th edition published 2011.

A range of respiratory disorders exist. Certain disorders may be characterised by particular events, e.g. apneas, hypopneas, and hyperpneas.

Obstructive Sleep Apnea (OSA), a form of Sleep Disordered Breathing (SDB), is characterized by events including

occlusion or obstruction of the upper air passage during sleep. It results from a combination of an abnormally small upper airway and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall during sleep. The condition causes the affected patient to stop breathing for periods typically of 30 to 120 seconds in duration, sometimes 200 to 300 times per night. It often causes excessive daytime somnolence, and it may cause cardiovascular disease and brain damage. The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem. See U.S. Pat. No. 4,944,310 (Sullivan).

Cheyne-Stokes Respiration (CSR) is another form of sleep disordered breathing. CSR is a disorder of a patient's respiratory controller in which there are rhythmic alternating periods of waxing and waning ventilation known as CSR cycles. CSR is characterised by repetitive de-oxygenation and re-oxygenation of the arterial blood. It is possible that CSR is harmful because of the repetitive hypoxia. In some patients CSR is associated with repetitive arousal from sleep, which causes severe sleep disruption, increased sympathetic activity, and increased afterload. See U.S. Pat. No. 6,532,959 (Berthon-Jones).

Respiratory failure is an umbrella term for respiratory disorders in which the lungs are unable to inspire sufficient oxygen or exhale sufficient CO_2 to meet the patient's needs. Respiratory failure may encompass some or all of the following disorders.

A patient with respiratory insufficiency (a form of respiratory failure) may experience abnormal shortness of breath on exercise.

Obesity Hyperventilation Syndrome (OHS) is defined as the combination of severe obesity and awake chronic hypercapnia, in the absence of other known causes for hypoventilation. Symptoms include dyspnea, morning headache and excessive daytime sleepiness.

Chronic Obstructive Pulmonary Disease (COPD) encompasses any of a group of lower airway diseases that have certain characteristics in common. These include increased resistance to air movement, extended expiratory phase of respiration, and loss of the normal elasticity of the lung. Examples of COPD are emphysema and chronic bronchitis. COPD is caused by chronic tobacco smoking (primary risk factor), occupational exposures, air pollution and genetic factors. Symptoms include: dyspnea on exertion, chronic cough and sputum production.

Neuromuscular Disease (NMD) is a broad term that encompasses many diseases and ailments that impair the functioning of the muscles either directly via intrinsic muscle pathology, or indirectly via nerve pathology. Some NMD patients are characterised by progressive muscular impairment leading to loss of ambulation, being wheelchair-bound, swallowing difficulties, respiratory muscle weakness and, eventually, death from respiratory failure. Neuromuscular disorders can be divided into rapidly progressive and slowly progressive: (i) Rapidly progressive disorders: Characterised by muscle impairment that worsens over months and results in death within a few years (e.g. Amyotrophic lateral sclerosis (ALS) and Duchenne muscular dystrophy (DMD) in teenagers); (ii) Variable or slowly progressive disorders: Characterised by muscle impairment that worsens over years and only mildly reduces life expectancy (e.g. Limb girdle, Facioscapulohumeral and Myotonic muscular dystrophy). Symptoms of respiratory failure in NMD include: increasing generalised weakness, dysphagia, dyspnea on exertion and at rest, fatigue, sleepiness, morning headache, and difficulties with concentration and mood changes.

Chest wall disorders are a group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage. The disorders are usually characterised by a restrictive defect and share the potential of long term hypercapnic respiratory failure. Scoliosis and/or kyphoscoliosis may cause severe respiratory failure. Symptoms of respiratory failure include: dyspnea on exertion, peripheral oedema, orthopnea, repeated chest infections, morning headaches, fatigue, poor sleep quality and loss of appetite.

A range of therapies have been used to treat or ameliorate such conditions. Furthermore, otherwise healthy individuals may take advantage of such therapies to prevent respiratory disorders from arising. However, these have a number of shortcomings.

5.2.2 Therapy

Continuous Positive Airway Pressure (CPAP) therapy has been used to treat Obstructive Sleep Apnea (OSA). The mechanism of action is that continuous positive airway pressure acts as a pneumatic splint and may prevent upper airway occlusion, such as by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall. Treatment of OSA by CPAP therapy may be voluntary, and hence patients may elect not to comply with therapy if they find devices used to provide such therapy one or more of: uncomfortable, difficult to use, expensive and aesthetically unappealing.

Non-invasive ventilation (NIV) provides ventilatory support to a patient through the upper airways to assist the patient breathing and/or maintain adequate oxygen levels in the body by doing some or all of the work of breathing. The ventilatory support is provided via a non-invasive patient interface. NIV has been used to treat CSR and respiratory failure, in forms such as OHS, COPD, NMD and Chest Wall disorders. In some forms, the comfort and effectiveness of these therapies may be improved.

Invasive ventilation (IV) provides ventilatory support to patients that are no longer able to effectively breathe themselves and may be provided using a tracheostomy tube. In some forms, the comfort and effectiveness of these therapies may be improved.

5.2.3 Treatment Systems

These therapies may be provided by a treatment system or device. Such systems and devices may also be used to diagnose a condition without treating it.

A treatment system may comprise a Respiratory Pressure Therapy Device (RPT device), an air circuit, a humidifier and a patient interface.

5.2.3.1 Patient Interface

A patient interface may be used to interface respiratory equipment to its wearer, for example by providing a flow of air to an entrance to the airways. The flow of air may be provided via a mask to the nose and/or mouth, a tube to the mouth or a tracheostomy tube to the trachea of a patient. Depending upon the therapy to be applied, the patient interface may form a seal, e.g., with a region of the patient's face, to facilitate the delivery of gas at a pressure at sufficient variance with ambient pressure to effect therapy, e.g., at a positive pressure of about 10 cmH_2O relative to ambient pressure. For other forms of therapy, such as the delivery of oxygen, the patient interface may not include a seal sufficient to facilitate delivery to the airways of a supply of gas at a positive pressure of about 10 cmH_2O.

Certain other mask systems may be functionally unsuitable for the present field. For example, purely ornamental masks may be unable to maintain a suitable pressure. Mask systems used for underwater swimming or diving may be configured to guard against ingress of water from an external higher pressure, but not to maintain air internally at a higher pressure than ambient.

Certain masks may be clinically unfavourable for the present technology e.g. if they block airflow via the nose and only allow it via the mouth.

Certain masks may be uncomfortable or impractical for the present technology if they require a patient to insert a portion of a mask structure in their mouth to create and maintain a seal via their lips.

Certain masks may be impractical for use while sleeping, e.g. for sleeping while lying on one's side in bed with a head on a pillow.

The design of a patient interface presents a number of challenges. The face has a complex three-dimensional shape. The size and shape of noses and heads varies considerably between individuals. Since the head includes bone, cartilage and soft tissue, different regions of the face respond differently to mechanical forces. The jaw or mandible may move relative to other bones of the skull. The whole head may move during the course of a period of respiratory therapy.

As a consequence of these challenges, some masks suffer from being one or more of obtrusive, aesthetically undesirable, costly, poorly fitting, difficult to use, and uncomfortable especially when worn for long periods of time or when a patient is unfamiliar with a system. Wrongly sized masks can give rise to reduced compliance, reduced comfort and poorer patient outcomes. Masks designed solely for aviators, masks designed as part of personal protection equipment (e.g. filter masks), SCUBA masks, or for the administration of anaesthetics may be tolerable for their original application, but nevertheless such masks may be undesirably uncomfortable to be worn for extended periods of time, e.g., several hours. This discomfort may lead to a reduction in patient compliance with therapy. This is even more so if the mask is to be worn during sleep.

CPAP therapy is highly effective to treat certain respiratory disorders, provided patients comply with therapy. If a mask is uncomfortable, or difficult to use a patient may not comply with therapy. Since it is often recommended that a patient regularly wash their mask, if a mask is difficult to clean (e.g., difficult to assemble or disassemble), patients may not clean their mask and this may impact on patient compliance.

While a mask for other applications (e.g. aviators) may not be suitable for use in treating sleep disordered breathing, a mask designed for use in treating sleep disordered breathing may be suitable for other applications.

For these reasons, patient interfaces for delivery of CPAP during sleep form a distinct field.

5.2.3.1.1 Seal-Forming Portion

Patient interfaces may include a seal-forming portion. Since it is in direct contact with the patient's face, the shape and configuration of the seal-forming portion can have a direct impact the effectiveness and comfort of the patient interface.

A patient interface may be partly characterised according to the design intent of where the seal-forming portion is to engage with the face in use. In one form of patient interface, a seal-forming portion may comprise two sub-portions to engage with respective left and right nares. In one form of patient interface, a seal-forming portion may comprise a single element that surrounds both nares in use. Such single element may be designed to for example overlay an upper lip region and a nasal bridge region of a face. In one form of patient interface a seal-forming portion may comprise an element that surrounds a mouth region in use, e.g. by forming a seal on a lower lip region of a face. In one form of patient interface, a seal-forming portion may comprise a single element that surrounds both nares and a mouth region in use. These different types of patient interfaces may be known by a variety of names by their manufacturer including nasal masks, full-face masks, nasal pillows, nasal puffs and oro-nasal masks. An oro-nasal mask may include a compact full-face mask without a forehead support. Alternatively an oro-nasal mask may include a full-face mask that seals around the entrance of the mouth and nose, wherein the nose seal includes a cradle that seals below the lateral cartilage.

A seal-forming portion that may be effective in one region of a patient's face may be inappropriate in another region, e.g. because of the different shape, structure, variability and sensitivity regions of the patient's face. For example, a seal on swimming goggles that overlays a patient's forehead may not be appropriate to use on a patient's nose.

Certain seal-forming portions may be designed for mass manufacture such that one design fit and be comfortable and effective for a wide range of different face shapes and sizes. To the extent to which there is a mismatch between the shape of the patient's face, and the seal-forming portion of the mass-manufactured patient interface, one or both must adapt in order for a seal to form.

One type of seal-forming portion extends around the periphery of the patient interface, and is intended to seal against the patient's face when force is applied to the patient interface with the seal-forming portion in confronting engagement with the patient's face. The seal-forming portion may include an air or fluid filled cushion, or a moulded or formed surface of a resilient seal element made of an elastomer such as a rubber. With this type of seal-forming portion, if the fit is not adequate, there will be gaps between the seal-forming portion and the face, and additional force will be required to force the patient interface against the face in order to achieve a seal.

Another type of seal-forming portion incorporates a flap seal of thin material positioned about the periphery of the mask so as to provide a self-sealing action against the face of the patient when positive pressure is applied within the mask. Like the previous style of seal forming portion, if the match between the face and the mask is not good, additional force may be required to achieve a seal, or the mask may leak. Furthermore, if the shape of the seal-forming portion does not match that of the patient, it may crease or buckle in use, giving rise to leaks.

Another type of seal-forming portion may comprise a friction-fit element, e.g. for insertion into a naris, however some patients find these uncomfortable.

Another form of seal-forming portion may use adhesive to achieve a seal. Some patients may find it inconvenient to constantly apply and remove an adhesive to their face.

A range of patient interface seal-forming portion technologies are disclosed in the following patent applications, assigned to ResMed Limited: WO 1998/004,310; WO 2006/074,513; WO 2010/135,785.

One form of nasal pillow is found in the Adam Circuit manufactured by Puritan Bennett. Another nasal pillow, or nasal puff is the subject of U.S. Pat. No. 4,782,832 (Trimble et al.), assigned to Puritan-Bennett Corporation.

ResMed Limited has manufactured the following products that incorporate nasal pillows: SWIFT™ nasal pillows mask, SWIFT™ II nasal pillows mask, SWIFT™ LT nasal pillows mask, SWIFT™ FX nasal pillows mask and MIRAGE LIBERTY™ full-face mask. The following patent applications, assigned to ResMed Limited, describe examples of nasal pillows masks: International Patent Application WO 2004/073,778 (describing amongst other things aspects of the ResMed Limited SWIFT™ nasal pillows), US Patent Application 2009/0044808 (describing amongst other things aspects of the ResMed Limited SWIFT™ LT nasal pillows); International Patent Applications WO 2005/063,328 and WO 2006/130,903 (describing amongst other things aspects of the ResMed Limited MIRAGE LIBERTY™ full-face mask); International Patent Application WO 2009/052,560 (describing amongst other things aspects of the ResMed Limited SWIFT™ FX nasal pillows).

5.2.3.1.2 Positioning and Stabilising

A seal-forming portion of a patient interface used for positive air pressure therapy is subject to the corresponding force of the air pressure to disrupt a seal. Thus a variety of techniques have been used to position the seal-forming portion, and to maintain it in sealing relation with the appropriate portion of the face.

One technique is the use of adhesives. See for example US Patent Application Publication No. US 2010/0000534. However, the use of adhesives may be uncomfortable for some.

Another technique is the use of one or more straps and/or stabilising harnesses. Many such harnesses suffer from being one or more of ill-fitting, bulky, uncomfortable and awkward to use. When designed to be worn on the patient's head, such harnesses may be referred to as headgear.

5.2.3.1.3 Pressurised Air Conduit

In one type of treatment system, a flow of pressurised air is provided to a patient interface through a conduit in an air circuit that fluidly connects to the patient interface so that, when the patient interface is positioned on the patient's face during use, the conduit extends out of the patient interface forwards away from the patient's face. This may sometimes be referred to as an "elephant trunk" style of interface.

Some patients find such interfaces to be unsightly and are consequently deterred from wearing them, reducing patient compliance. Additionally, conduits connecting to an interface at the front of a patient's face may sometimes be vulnerable to becoming tangled up in bed clothes.

5.2.3.1.4 Pressurised Air Conduit Used for Positioning/Stabilising the Seal-Forming Structure

An alternative type of treatment system which seeks to address these problems comprises a patient interface in which a tube that delivers pressurised air to the patient's airways also functions as part of the headgear to position and stabilise the seal-forming portion of the patient interface to the appropriate part of the patient's face. This type of patient interface may be referred to as incorporating 'headgear tubing' or 'conduit headgear'. Such patient interfaces allow the conduit in the air circuit providing the flow of pressurised air from a respiratory pressure therapy device to connect to the patient interface in a position other than in front of the patient's face. One example of such a treatment system is disclosed in US Patent Publication No. US 2007/0246043, the contents of which are incorporated herein by reference, in which the conduit connects to a tube in the patient interface through a port positioned in use on top of the patient's head.

The Philips DreamWear™ nasal mask includes such headgear tubing. One problem with this mask is that the length of the headgear tubes cannot be adjusted. Consequently the DreamWear™ mask is supplied in different sizes to cater for different sized patient faces. However, this creates complexity and cost to manufacture the DreamWear™ mask and larger packaging. Additionally, the supply of discretely sized masks limits the extent to which differently sized patient heads can be accommodated, for example, if the patient's head size falls between or outside the mask sizes provided.

Patient interfaces incorporating headgear tubing may provide some advantages, for example avoiding a conduit connecting to the patient interface at the front of a patient's face, which may be unsightly and obtrusive. However, it is desirable for patient interfaces incorporating headgear tubing to be comfortable for a patient to wear over a prolonged duration when the patient is asleep while forming an effective seal with the patient's face.

5.2.3.2 Respiratory Pressure Therapy (RPT) Device

Air pressure generators are known in a range of applications, e.g. industrial-scale ventilation systems. However, air pressure generators for medical applications have particular requirements not fulfilled by more generalised air pressure generators, such as the reliability, size and weight requirements of medical devices. In addition, even devices designed for medical treatment may suffer from shortcomings, pertaining to one or more of: comfort, noise, ease of use, efficacy, size, weight, manufacturability, cost, and reliability.

One known RPT device used for treating sleep disordered breathing is the S9 Sleep Therapy System, manufactured by ResMed Limited. Another example of an RPT device is a ventilator. Ventilators such as the ResMed Stellar™ Series of Adult and Paediatric Ventilators may provide support for invasive and non-invasive non-dependent ventilation for a range of patients for treating a number of conditions such as but not limited to NMD, OHS and COPD.

5.2.3.3 Humidifier

Delivery of a flow of air without humidification may cause drying of airways. The use of a humidifier with an RPT device and the patient interface produces humidified gas that minimizes drying of the nasal mucosa and increases patient airway comfort. In addition in cooler climates, warm air applied generally to the face area in and about the patient interface is more comfortable than cold air.

6 BRIEF SUMMARY OF THE TECHNOLOGY

The present technology is directed towards providing medical devices used in the diagnosis, amelioration, treatment, or prevention of respiratory disorders having one or more of improved comfort, cost, efficacy, ease of use and manufacturability.

A first aspect of the present technology relates to apparatus used in the diagnosis, amelioration, treatment or prevention of a respiratory disorder.

An aspect of certain forms of the present technology is to provide methods and/or apparatus that improve the compliance of patients with respiratory therapy.

One form of the present technology comprises a patient interface for delivery of a supply of pressurised breathable gas to an entrance of a patient's airways.

Another aspect of one form of the present technology comprises a positioning and stabilising structure to hold a seal-forming structure in a therapeutically effective position on a head of a patient. The seal-forming structure may be constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The at least one gas delivery tube may be constructed and arranged to contact, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head. The positioning and stabilising structure may comprise an adjustment mechanism for adjustment of a length of the at least one gas delivery tube to enable the positioning and stabilising structure to fit different size heads. The positioning and stabilising structure may comprise a bias mechanism to impart a biasing force along at least a part of a length of the at least one gas delivery tube to urge the seal-forming structure towards the entrance of the patient's airways in use.

Another aspect of one form of the present technology comprises a patient interface comprising a plenum chamber pressurisable to a therapeutic pressure of at least 4 cmH_2O above ambient air pressure. The plenum chamber may include a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient. The patient interface may comprise a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares. The seal-forming structure may be constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use. The patient interface may comprise a connection port to fluidly connect, in use, with an air circuit connected to the flow of air. The connection port may be located, in use, proximal a top, side or rear portion of a patient's head. The patient interface may comprise a positioning and stabilising structure to hold the seal-forming structure in a therapeutically effective position on the patient's head. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver a flow of air to the entrance of a patient's airways via the seal-forming structure. The at least one gas delivery tube may be constructed and arranged to contact, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head. The positioning and stabilising structure may comprise an adjustment mechanism for adjustment of a length of the at least one gas delivery tube to enable the positioning and stabilising structure to fit different size heads. The positioning and stabilising structure may comprise a bias mechanism to impart a biasing force along at least a part of a length of the at least one gas delivery tube to urge the seal-forming structure towards the entrance of the patient's airways in use.

Another aspect of one form of the present technology comprises a positioning and stabilising structure to hold a seal-forming structure in a therapeutically effective position on a head of a patient. The seal-forming structure may be constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use. The positioning and stabilising structure may comprise at least one tie. The at least one tie may be configured to contact the patient's head in use. The at least one tie may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The at least one gas delivery tube may be constructed and arranged to overlie, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head. The positioning and stabilising structure may comprise an adjustment mechanism for adjustment of the at least one tie to enable the positioning and stabilising structure to fit different size heads. The positioning and stabilising structure may be configured such that, in use, the adjustment mechanism is positioned out of contact with a patient's face.

Another aspect of one form of the present technology comprises a patient interface comprising a plenum chamber pressurisable to a therapeutic pressure of at least 4 cmH_2O above ambient air pressure. The plenum chamber may include a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient. The patient interface may comprise a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares. The seal-forming structure may be constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use. The patient interface may comprise a connection port to fluidly connect, in use, with an air circuit connected to the flow of air. The connection port may be located, in use, proximal a top, side or rear portion of a patient's head. The patient interface may comprise a positioning and stabilising structure to hold the seal-forming structure in a therapeutically effective position on the patient's head. The positioning and stabilising structure may comprise at least one tie. The at least one tie may be configured to contact the patient's head in use. The at least one tie may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The at least one gas delivery tube may be constructed and arranged to overlie, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head. The positioning and stabilising structure may comprise an adjustment mechanism for adjustment of the at least one tie to enable the positioning and stabilising structure to fit different size heads. The positioning and stabilising structure may be configured such that, in use, the adjustment mechanism is positioned out of contact with a patient's face.

Another aspect of one form of the present technology comprises a patient interface comprising a plenum chamber pressurisable to a therapeutic pressure of at least 4 cmH_2O above ambient air pressure. The plenum chamber may include a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient. The patient interface may comprise a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares. The seal-forming structure may be constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use. The patient interface may comprise a positioning and stabilising structure to hold the seal-forming structure in a therapeutically effective position on the patient's head. The positioning and stabilising structure may comprise a first tube portion constructed and arranged to overlay a region of the patient's head superior to an otobasion superior of the patient's head in use. The positioning and stabilising structure may comprise a tie portion to overlay or lie inferior to the occipital bone of the patient's head in use. The patient interface may comprise a vent structure to allow a continuous flow of gases exhaled by the patient from an interior of the plenum chamber to ambient, said vent structure being sized and shaped to maintain the therapeutic pressure in the plenum chamber in use. The first tube portion may be configured to conduct at least a portion of the flow of air for breathing by the patient. The first tube portion may be configured to be in tension in use. The first tube portion may include a lengthwise adjustment mechanism.

Another aspect of one form of the present technology comprises a positioning and stabilising structure to hold a seal-forming structure in a therapeutically effective position on a head of a patient. The seal-forming structure may be constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use. The positioning and stabilising structure may comprise a first conduit portion constructed and arranged to overlay a region of the patient's head superior to an otobasion superior of the patient's head in use. The positioning and stabilising structure may comprise a tie portion to overlay or lie inferior to the occipital bone of the patient's head in use. The first conduit portion may be configured to conduct at least a portion of the flow of air for breathing by the patient. The first conduit portion may be configured to be in tension in use. The first conduit portion may include a lengthwise adjustment mechanism.

Another aspect of one form of the present technology comprises a patient interface comprising a plenum chamber pressurisable to a therapeutic pressure of at least 4 cmH_2O above ambient air pressure. The plenum chamber may include a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient. The patient interface may comprise a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares. The seal-forming structure may be constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use. The patient interface may comprise a positioning and stabilising structure to provide an elastic force to hold a seal-forming structure in a therapeutically effective position on a patient's head for sealed delivery of the flow of air at the therapeutic pressure. The positioning and stabilising structure may comprise a tie. The tie may be constructed and arranged so that at least a portion of the tie overlies a region of the patient's head superior to an otobasion superior of the patient's head in use. The tie may comprise a length-adjustable gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The gas delivery tube may be configured to contact a portion of the patient's head in use. The positioning and stabilising structure may comprise a bias mechanism to impart a biasing force upon the length-adjustable gas delivery tube to urge the seal forming structure towards the entrance of the patient's airways in use.

Another aspect of one form of the present technology comprises a positioning and stabilising structure to hold a seal-forming structure in a therapeutically effective position on a head of a patient. The seal-forming structure may be constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use. The positioning and stabilising structure may comprise a tie. The tie may be constructed and arranged so that at least a portion of the tie overlies a region of the patient's head superior to an otobasion superior of the patient's head in use. The tie may comprise a length-adjustable gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The gas delivery tube may be configured to contact a portion of the patient's head in use. The positioning and stabilising structure may comprise a bias mechanism to impart a biasing force upon the length-adjustable gas delivery tube to urge the seal forming structure towards the entrance of the patient's airways in use.

Another aspect of one form of the present technology comprises an inflatable positioning and stabilising structure to maintain a seal at an entrance of the patient's airways formed by a seal-forming structure of a patient interface for sealed delivery of a flow of air at a continuously positive pressure with respect to ambient air pressure and configured to maintain a therapy pressure in a range of about 4 cmH_2O to about 30 cmH_2O above ambient air pressure in use, throughout the patient's respiratory cycle, while the patient is sleeping, to ameliorate sleep disordered breathing. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The positioning and stabilising structure may also comprise an adjustment mechanism to enable dimensional adjustment of the positioning and stabilising structure. The positioning and stabilising structure may also comprise a bias mechanism to impart a biasing force upon the adjustment mechanism and urge the seal-forming structure towards the entrance of the patient's airways.

Another aspect of one form of the present technology comprises a patient interface for delivery of a supply of pressurised air at a continuously positive pressure with respect to ambient air pressure to an entrance of a patient's airways, the patient interface being configured to maintain a therapy pressure in a range of about 4 cmH_2O to about 30 cmH_2O above ambient air pressure in use, throughout the patient's respiratory cycle, while the patient is sleeping, to ameliorate sleep disordered breathing. The patient interface may comprise a connection port to fluidly connect, in use, with an air circuit connected to the supply of pressurised air, the connection port being located, in use, proximal a top, side or rear portion of a patient's head. The patient interface may also comprise a seal-forming structure to seal with an area surrounding the entrance to the patient's airways. The patient interface may also comprise an inflatable positioning and stabilising structure to maintain the seal formed by the seal-forming structure. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure.

Another aspect of a related form of the present technology comprises a patient interface comprising a positioning and stabilising structure comprising an adjustment mechanism to enable dimensional adjustment of the positioning and stabilising structure.

Another aspect of a related form of the present technology comprises a patient interface comprising a bias mechanism to impart a biasing force upon the adjustment mechanism and urge the seal-forming structure towards the entrance of the patient's airways.

Another aspect of one form of the present technology comprises an inflatable positioning and stabilising structure to maintain a seal at an entrance of the patient's airways formed by a seal-forming structure of a patient interface for sealed delivery of a flow of air at a continuously positive pressure with respect to ambient air pressure and configured to maintain a therapy pressure in a range of about 4 cmH_2O to about 30 cmH_2O above ambient air pressure in use, throughout the patient's respiratory cycle, while the patient is sleeping, to ameliorate sleep disordered breathing. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The positioning and stabilising structure may also comprise an adjustment mechanism to enable dimensional adjustment of the positioning and stabilising structure. The positioning and stabilising structure may be configured such that, in use, the adjustment mechanism is positioned out of contact with a patient's cheek region.

Another aspect of one form of the present technology comprises a patient interface for delivery of a supply of pressurised air at a continuously positive pressure with respect to ambient air pressure to an entrance of a patient's airways, the patient interface being configured to maintain a therapy pressure in a range of about 4 cmH_2O to about 30 cmH_2O above ambient air pressure in use, throughout the patient's respiratory cycle, while the patient is sleeping, to ameliorate sleep disordered breathing. The patient interface may comprise a positioning and stabilising structure. The positioning and stabilising structure may comprise at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure. The positioning and stabilising structure may also comprise an adjustment mechanism to enable dimensional adjustment of the positioning and stabilising structure. The positioning and stabilising structure may be configured such that, in use, the adjustment mechanism is positioned out of contact with a patient's cheek region.

Another aspect of certain forms of the present technology is a system for treating a respiratory disorder comprising a patient interface according to any one or more of the other aspects of the present technology, an air circuit and a source of air at positive pressure.

Another aspect of one form of the present technology is a patient interface that is moulded or otherwise constructed with a perimeter shape which is complementary to that of an intended wearer.

Another aspect of certain forms of the present technology is a patient interface comprising a seal-forming structure configured to leave the patient's mouth uncovered in use.

Another aspect of certain forms of the present technology is a patient interface comprising a seal-forming structure configured so that no part of the seal-forming structure enters the mouth in use.

Another aspect of certain forms of the present technology is a patient interface comprising a seal-forming structure configured so that the seal-forming structure does not extend internally of the patient's airways.

Another aspect of certain forms of the present technology is a patient interface comprising a seal-forming structure configured so that the seal-forming structure does not extend below a mental protuberance region in use.

Another aspect of certain forms of the present technology is a patient interface constructed and arranged to leave a patient's eyes uncovered in use.

Another aspect of certain forms of the present technology is a patient interface constructed and arranged to allow a patient to breathe ambient air in the event of a power failure.

Another aspect of certain forms of the present technology is a patient interface comprising a seal forming structure configured to form a seal on an underside of a patient's nose without contacting a nasal bridge region of the patient's nose.

Another aspect of certain forms of the present technology is a patient interface comprising a vent and a plenum chamber, wherein the patient interface is constructed and arranged so that gases from an interior of the plenum chamber may pass to ambient via the vent.

Another aspect of certain forms of the present technology is a patient interface constructed and arranged so that a patient may lie comfortably in a side or lateral sleeping position, in use of the patient interface.

Another aspect of certain forms of the present technology is a patient interface constructed and arranged so that a patient may lie comfortably in a supine sleeping position, in use of the patient interface.

Another aspect of certain forms of the present technology is a patient interface constructed and arranged so that a patient may lie comfortably in a prone sleeping position, in use of the patient interface.

An aspect of certain forms of the present technology is a medical device that is easy to use, e.g. by a person who does not have medical training, by a person who has limited dexterity, vision or by a person with limited experience in using this type of medical device.

An aspect of one form of the present technology is a patient interface that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment. An aspect of one form of the present technology is a humidifier tank that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment.

Of course, portions of the aspects may form sub-aspects of the present technology. Also, various ones of the sub-aspects and/or aspects may be combined in various manners and also constitute additional aspects or sub-aspects of the present technology.

Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

7 BRIEF DESCRIPTION OF THE DRAWINGS

The present technology is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to similar elements including:

7.1 Treatment Systems

FIG. **1**A shows a system including a patient **1000** wearing a patient interface **3000**, in the form of a nasal pillows, receiving a supply of air at positive pressure from an RPT device **4000**. Air from the RPT device **4000** is humidified in a humidifier **5000**, and passes along an air circuit **4170** to the patient **1000**. A bed partner **1100** is also shown.

FIG. **1**B shows a system including a patient **1000** wearing a patient interface **3000**, in the form of a nasal mask, receiving a supply of air at positive pressure from an RPT device **4000**. Air from the RPT device is humidified in a humidifier **5000**, and passes along an air circuit **4170** to the patient **1000**.

FIG. **1**C shows a system including a patient **1000** wearing a patient interface **3000**, in the form of a full-face mask, receiving a supply of air at positive pressure from an RPT device **4000**. Air from the RPT device is humidified in a humidifier **5000**, and passes along an air circuit **4170** to the patient **1000**.

7.2 Respiratory System and Facial Anatomy

FIG. **2**A shows an overview of a human respiratory system including the nasal and oral cavities, the larynx, vocal folds, oesophagus, trachea, bronchus, lung, alveolar sacs, heart and diaphragm.

FIG. **2**B shows a view of a human upper airway including the nasal cavity, nasal bone, lateral nasal cartilage, greater alar cartilage, nostril, lip superior, lip inferior, larynx, hard palate, soft palate, oropharynx, tongue, epiglottis, vocal folds, oesophagus and trachea.

FIG. **2**C is a front view of a face with several features of surface anatomy identified including the lip superior, upper vermilion, lower vermilion, lip inferior, mouth width, endocanthion, a nasal ala, nasolabial sulcus and cheilion. Also indicated are the directions superior, inferior, radially inward and radially outward.

FIG. **2**D is a side view of a head with several features of surface anatomy identified including glabella, sellion, pronasale, subnasale, lip superior, lip inferior, supramenton, nasal ridge, alar crest point, otobasion superior and otobasion inferior. Also indicated are the directions superior & inferior, and anterior & posterior.

FIG. **2**E is a further side view of a head. The approximate locations of the Frankfort horizontal and nasolabial angle are indicated. The coronal plane is also indicated.

FIG. **2**F shows a base view of a nose with several features identified including naso-labial sulcus, lip inferior, upper Vermilion, naris, subnasale, columella, pronasale, the major axis of a naris and the sagittal plane.

7.3 Patient Interface

FIGS. **3**A, **3**B, **3**C, **3**D and **3**E show patient interfaces **3000** comprising positioning and stabilising structures **3300** in accordance with certain forms of the present technology.

FIG. **3**F shows a plan view of the patient interface **3000** shown in FIGS. **3**C, **3**D and **3**E.

FIG. **3**G shows in cross-section a portion of the patient interface **3000** shown in FIG. **3**F.

FIG. **3**H shows a longitudinal section of a headgear tube **3350** of a patient interface **3000**.

FIG. **3**I shows a plot of an exemplary force-extension characteristic of a headgear tube **3350** of a patient interface **3000**.

FIG. **3**J shows a side view of the patient interface shown in FIGS. **3**C, **3**D and **3**E worn by a patient with a connection port **3600** in a central position and, in phantom, in forward and rearward positions.

FIG. **3**K shows a side view of the patient interface shown in FIGS. **3**C, **3**D and **3**E worn by a patient with one head size and, in phantom, a patient with a larger head size.

FIG. **3**L shows a side view of the patient interface shown in FIGS. **3**C, **3**D and **3**E worn by a patient with an adjustment mechanism **3360** positioned centrally and, in phantom, forwardly and rearwardly.

FIGS. **4**A, **4**B, **4**C, **4**D and **4**E show cushion assemblies **3150** of a patient interface **3000** according to certain forms of the present technology.

FIG. **5** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having a fold portion **3364** and a strap **3390** in accordance with one form of the present technology.

FIGS. **5**A and **5**B show in cross-section the fold portion **3364** of the patient interface **3000** of FIG. **5** with rolling fold portion **3366** folded over adjacent tube portion **3368** to varying degrees.

FIG. **6** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** comprising flexible tubes **3350** in accordance with one form of the present technology.

FIGS. **7**A, **7**B and **7**C show patient interfaces **3000** comprising a positioning and stabilising structure **3300** having first and second tube portions **3370** and **3372** in accordance with certain forms of the present technology.

FIG. **8** shows part of a patient interface **3000** comprising a positioning and stabilising structure **3300** having discretely adjustable first and second tube portions **3370** and **3372** in accordance with one form of the present technology.

FIG. **9** shows part of a patient interface comprising a positioning and stabilising structure **3300** having first and second tube portions **3370** and **3372** in accordance with one form of the present technology.

FIG. **10**A shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having an adjustment mechanism **3360** in accordance with one form of the present technology.

FIG. **10**B shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having threaded tube sections **3380** and **3382** in accordance with one form of the present technology

FIG. **11** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having replaceable tube portions **3385** and **3386** in accordance with one form of the present technology.

FIG. **12** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having insertable tube portions **3387** in accordance with one form of the present technology.

FIG. **13** shows part of a tube **3350** for a patient interface comprising a stretchable tube section **3355** in accordance with one form of the present technology.

FIG. **14** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having band **3395** in accordance with one form of the present technology.

FIG. **15** shows a part of a patient interface comprising replaceable loop insert members **3410** and **3411** in accordance with one form of the present technology.

FIG. **16** shows a part of a patient interface comprising an inflatable loop insert member **3420** in accordance with one form of the present technology.

FIG. **17** shows a patient interface **3000** comprising a positioning and stabilising structure **3300** having concertina tube sections **3362** and an elastic sleeve **3340** in accordance with one form of the present technology.

7.4 RPT Device

FIG. **18** shows an RPT device in accordance with one form of the present technology.

7.5 Humidifier

FIG. **19**A shows an isometric view of a humidifier in accordance with one form of the present technology.

FIG. **19**B shows an isometric view of a humidifier in accordance with one form of the present technology, showing a humidifier reservoir **5110** removed from the humidifier reservoir dock **5130**.

8 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

Before the present technology is described in further detail, it is to be understood that the technology is not limited to the particular examples described herein, which may vary. It is also to be understood that the terminology used in this disclosure is for the purpose of describing only the particular examples discussed herein, and is not intended to be limiting.

The following description is provided in relation to various examples which may share one or more common characteristics and/or features. It is to be understood that one or more features of any one example may be combinable with one or more features of another example or other examples. In addition, any single feature or combination of features in any of the examples may constitute a further example.

8.1 Therapy

In one form as shown in FIG. **1**A, the present technology comprises a method for treating a respiratory disorder comprising the step of applying positive pressure to the entrance of the airways of a patient **1000**.

8.2 Treatment Systems

In one form, the present technology comprises an apparatus or device for treating a respiratory disorder. The apparatus or device may comprise an RPT device **4000** for supplying pressurised air to the patient **1000** via an air circuit **4170** to a patient interface **3000**. FIGS. **1**A, **1**B and **1**C illustrate treatment systems which utilise different forms of patient interface **3000**

8.3 Patient Interface

With reference to FIG. **3**A, a non-invasive patient interface **3000** in accordance with one aspect of the present technology comprises the following functional aspects: a cushion assembly **3150**, a positioning and stabilising structure **3300** and a connection port **3600** for connection to air circuit **4170**. In some forms a functional aspect may be provided by one or more physical components. In some forms, one physical component may provide one or more functional aspects.

The cushion assembly **3150** comprises a seal-forming structure **3100** and a plenum chamber **3200**. In use the plenum chamber **3200** receives the supply of air at positive pressure from the air circuit **4170** and the seal-forming structure **3100** is arranged to seal with an area surrounding an entrance to the airways of the patient so as to facilitate the supply of air at positive pressure to the airways.

8.3.1 Seal-Forming Structure

In one form of the present technology, a seal-forming structure **3100** provides a seal-forming surface, and may additionally provide a cushioning function.

A seal-forming structure **3100** in accordance with the present technology may be constructed from a soft, flexible, resilient material such as silicone.

The seal-forming structure **3100** may be non-invasive, i.e. does not extend internally of the patient's airways. In some forms of the technology, no part of the seal-forming structure **3100** enters the patient's mouth in use. In some forms of the technology, the seal-forming structure **3100** is configured to leave the patient's mouth uncovered in use. In some forms of the technology, the seal-forming structure **3100** does not cover the patient's eyes in use.

In one form, the seal-forming structure **3100** comprises a sealing flange and a support flange. The sealing flange comprises a relatively thin member with a thickness of less than about 1 mm, for example about 0.25 mm to about 0.45

mm that extends around the perimeter of the plenum chamber **3200**. Support flange may be relatively thicker than the sealing flange. The support flange is disposed between the sealing flange and the marginal edge of the plenum chamber **3200**, and extends at least part of the way around the perimeter. The support flange is or includes a spring-like element and functions to support the sealing flange from buckling in use. In use the sealing flange can readily respond to system pressure in the plenum chamber **3200** acting on its underside to urge it into tight sealing engagement with the face.

In one form as shown in FIG. **1**A, the seal-forming portion of the non-invasive patient interface **3000** comprises a pair of nasal puffs, or nasal pillows, each nasal puff or nasal pillow being constructed and arranged to form a seal with a respective naris of the nose of a patient. A nasal pillows patient interface **3000** is also shown in FIG. **3**A.

Nasal pillows in accordance with an aspect of the present technology include: a frusto-cone, at least a portion of which forms a seal on an underside of the patient's nose, a stalk, a flexible region on the underside of the frusto-cone and connecting the frusto-cone to the stalk. In addition, the structure to which the nasal pillow of the present technology is connected includes a flexible region adjacent the base of the stalk. The flexible regions can act in concert to facilitate a universal joint structure that is accommodating of relative movement both displacement and angular of the frusto-cone and the structure to which the nasal pillow is connected. For example, the frusto-cone may be axially displaced towards the structure to which the stalk is connected.

In one form, the non-invasive patient interface **3000** comprises a seal-forming portion that forms a seal in use on an upper lip region (that is, the lip superior), a nasal bridge region and a cheek region of the patient's face. This is the case, for example, with the patient interface **3000** shown in FIG. **1**B. This seal-forming portion delivers a supply of air or breathable gas to both nares of patient **1000** through a single orifice. This type of seal-forming structure may be referred to as a "nasal cushion" or "nasal mask".

In another form, the seal-forming structure is configured to form a seal in use with the underside of the nose around the nares and optionally with the lip superior. This type of seal-forming structure may be referred to as a "nasal cradle cushion" or "sub-nasal mask". The shape of the seal-forming structure may be configured to match or closely follow the underside of the patient's nose, i.e. the profile and angel of the seal-forming structure may be substantially parallel to the patient's naso-labial angle. In one form of nasal cradle cushion, the seal-forming structure comprises a septum member defining two orifices, each of which, in use, supply air or breathable gas to a different one of the patient's nares. The septum member may be configured to contact or seal against the patient's columella in use. In some forms of the technology, the seal-forming structure **3100** is configured to form a seal on an underside of the patient's nose without contacting a nasal bridge region of the patient's nose.

In one form the non-invasive patient interface **3000** comprises a seal-forming portion that forms a seal in use on a chin-region, a nasal bridge region and a cheek region of the patient's face. This is the case, for example, with the patient interface **3000** shown in FIG. **1**C. This seal-forming portion delivers a supply of air or breathable gas to both nares and mouth of patient **1000** through a single orifice. This type of seal-forming structure may be referred to as a "full-face mask".

In another form the non-invasive patient interface **3000** comprises a nasal seal-forming structure **3170** in the manner of a nasal cushion or nasal cradle cushion and an oral seal-forming structure **3180** that is configured to form a seal in use around the mouth of a patient (which may be referred to as a "mouth cushion" or "oral mask"). In such a mask air or breathable is supplied in use through separate orifices to the patient's nares and the patient's mouth. This type of seal-forming structure **3100** may be referred to as an "oro-nasal mask". In one form, the nasal seal-forming structure **3170** and oral seal-forming structure **3180** are integrally formed as a single component. This is the case, for example, with the cushion assembly **3150** shown in FIGS. **4**A, **4**B and **4**C. Alternatively, the nasal seal-forming structure **3170** and oral seal-forming structure **3180** may be formed separately and are configured to be attached together, either directly or indirectly, for example by connecting together frames attached to each cushion. For example, the nasal seal-forming structure **3170** and the oral seal-forming structure **3180** may be configured to be detached and re-attached in modular fashion. This enables the patient interface to be converted from an oro-nasal mask to a nasal mask or sub-nasal mask and vice versa, as desired by the patient and/or physician. This is the case, for example, with the cushion assembly **3150** shown in FIGS. **4**D and **4**E.

In some forms of the technology, the seal-forming structure **3100** is configured so that the seal-forming structure does not extend below a mental protuberance region of the patient's head in use.

Unless clearly specified otherwise, embodiments of patient interface according to the present technology may comprise any of the above types of seal-forming structure.

In certain forms of the present technology, a seal-forming structure **3100** is configured to correspond to a particular size of head and/or shape of face. For example one form of a seal-forming structure **3100** is suitable for a large sized head, but not a small sized head. In another example, a form of seal-forming structure **3100** is suitable for a small sized head, but not a large sized head.

8.3.2 Plenum Chamber

The plenum chamber **3200** receives, in use, pressurised breathable gas and is pressurised at a pressure above ambient pressure. In some forms of the present technology, the plenum chamber **3200** has a perimeter **3210** that is shaped to be complementary to the surface contour of the face of an average person in the region where a seal will form in use. In use, a marginal edge of the plenum chamber **3200** is positioned in close proximity to an adjacent surface of the face. Actual contact with the face is provided by the seal-forming structure **3100**. The seal-forming structure **3100** may extend in use about the entire perimeter of the plenum chamber **3200**.

The plenum chamber **3200** may receive the pressurised breathable gas through a plenum chamber inlet port that is sized and structured to receive the gas from another part of the patient interface **3000**.

8.3.3 Positioning and Stabilising Structure

The seal-forming structure **3100** of the patient interface **3000** of the present technology may be held in sealing position in use by the positioning and stabilising structure **3300**. Positioning and stabilising structure **3300** may be referred to as "headgear" since it engages the patient's head in order to hold the patient interface **3000** in a sealing position.

In one form of the present technology, a positioning and stabilising structure **3300** is provided that is configured in a manner consistent with being worn by a patient while sleeping. In one example the positioning and stabilising structure **3300** has a low profile, or cross-sectional thickness, to reduce the perceived or actual bulk of the apparatus.

The positioning and stabilising structure **3300** may comprise at least one tie. A tie will be understood to be a structure designed to resist tension. In use, a tie is part of the positioning and stabilising structure **3300** that is under tension. Some ties will impart an elastic force as a result of this tension, as will be described. A tie may act to maintain the seal-forming structure **3100** in a therapeutically effective position on the patient's head. In certain forms of the present technology, the positioning and stabilising structure **3300** may comprise ties in the form of headgear tubes **3350** and/or headgear straps, as will now be described.

8.3.3.1 Headgear Tubing

In the form of the present technology illustrated in FIG. **3**A, the positioning and stabilising structure **3300** comprises at least one tube **3350** that delivers pressurised air received from a conduit forming part of the air circuit **4170** from the RPT device to the patient's airways, for example through the plenum chamber **3200** and seal-forming structure **3100**. The tubes **3350** are an integral part of the headgear **3300** of patient interface **3000** to position and stabilise the seal-forming structure **3100** of the patient interface to the appropriate part of the patient's face (for example, the nose and/or mouth). This allows the conduit of air circuit **4170** providing the flow of pressurised air to connect to a connection port **3600** of the patient interface in a position other than in front of the patient's face which may be unsightly to some people.

Since air can be contained and passed through tubes **3350** in order to deliver pressurised air from the air circuit **4170** to the patient's airways, the positioning and stabilising structure **3300** may be described as being inflatable. It will be understood that an inflatable positioning and stabilising structure **3300** does not require all components of the positioning and stabilising structure **3300** to be inflatable.

In certain forms of the present technology, the patient interface **3000** may comprise a connection port **3600** located proximal a top, side or rear portion of a patient's head. For example, in the form of the present technology illustrated in FIG. **3**A, the connection port **3600** is located on top of the patient's head. Patient interfaces in which the connection port is not positioned in front of the patient's face may be advantageous as some patients find a conduit that connects to a patient interface in front of the face to be unsightly and obtrusive. For example, a conduit connecting to a patient interface in front of the face may be prone to being tangled up in bedclothes or bed linen, particularly if the conduit extends downwardly from the patient interface in use. Forms of the technology with a patient interface with a connection port positioned proximate the top of the patient's head in use may make it easier or more comfortable for a patient to lie or sleep in one or more of the following positions: in a side or lateral position; in a supine position (i.e. on their back, facing generally upwards); and in a prone position (i.e. on their front, facing generally downwards). Moreover, connecting a conduit to the front of a patient interface may also cause a problem known as tube drag, wherein the conduit may provide an undesired drag force upon the patient interface thereby causing dislodgement away from the face.

In the example of FIG. **3**A, the at least one tube **3350** extends between the cushion assembly **3150** from the connection port **3600** across the patient's cheek region and above the patient's ear, i.e. a portion of tube **3350** that connects to cushion assembly **3150** overlays a maxilla region of the patient's head in use and a portion of tube **3350** overlays a region of the patient's head superior to the otobasion superior on the patient's head.

In the form of the present technology illustrated in FIG. **3**A, the positioning and stabilising structure **3300** comprises two tubes **3350**, each tube being positioned in use on different sides of the patient's head and extending across the respective cheek region, above the respective ear (superior to the otobasion superior on the patient's head) to the connection port **3600** on top of the patient's head. This form of technology may be advantageous because, if a patient sleeps on the side of their head and one of the tubes in compressed to block or partially block the flow of gas along the tube, the other tube remains open to supply pressurised gas to the patient. In other embodiments of the technology, the patient interface may comprise a different number of tubes, for example one tube, or three or more tubes. In one example in which the patient interface has one tube **3350**, the single tube **3350** is positioned on one side of the patient's head in use (e.g. across one cheek region) and a strap forms part of the positioning and stabilising structure **3300** and is positioned on the other side of the patient's head in use (e.g. across the other region) to assist in securing the patient interface **3000** on the patient's head.

In the form of the technology shown in FIG. **3**A the two tubes **3350** are fluidly connected at their upper end to each other and to connection port **3600**. In one embodiment, the two tubes are integrally formed while in other embodiments the tubes are separate components that are connected together in use and may be disconnected, for example for cleaning or storage. Where separate tubes are used they may be indirectly connected together, for example each may be connected to a T-shaped conduit having two conduit arms each fluidly connectable to the tubes **3350** and a third conduit arm or opening acting as the connection port **3600** and connectable in use to the air circuit **4170**.

The tubes **3350** may be formed of a semi-rigid material such as an elastomeric material, e.g. silicone. The tubes may have a natural, preformed shape and be able to be bent or moved into another shape if a force is applied to the tubes. For example, the tubes may be generally arcuate or curved in a shape approximating the contours of a patient's head between the top of the head and the nasal or oral region.

The exemplary form of the technology illustrated in FIG. **3**A has tubes **3350** which curve around the upper part of the patient's head from the upper end of the tubes **3350** that connect to connection port **3600** on top of the head to the point at which the rear headgear strap **3310** connects to the tubes **3350** substantially without any curvature in the sagittal plane. In between the point at which the rear headgear strap **3310** connects to the tubes **3350** and the lower ends of the tubes **3350** where they connect with the cushion assembly **3150** in front of the patient's airways under the nose, the tubes **3350** curve forwards between the patient's ears and eyes and across the cheek region. The radius of curvature of this section of the tubes **3350** may be in the range 60-100 mm, for example 70-90 mm, for example 80 mm. The lower end of the tubes **3350** and the section of the tubes **3350** at which the rear headgear strap **3310** connects to the tubes **3350** may subtend an angle in the range 65-90°, for example 75-80°.

In certain forms of the technology, one or more portions of the tubes **3350** may be rigidised by one or more rigidising or stiffening elements. Examples of rigidising elements include: sections of the tubes **3350** that are comparatively thicker than other sections; sections of the tubes **3350** that are formed from a material that is comparatively more rigid that the material forming other sections; and a rigid member attached to the inside, outside or embedded in a section of tube. The use of such rigidising elements helps to control how the positioning and stabilising structure **3300** will function in use, for example where the tubes **3350** is more likely to deform if forces are applied to them and where the shape of the tubes **3350** is more likely to be maintained if forces are applied. The selection of where such rigidising elements are positioned in the tubes **3350** can therefore help to promote comfort when the patient interface **3000** is worn and can help to maintain a good seal at the seal-forming structure during use. Rigidising or stiffening elements may be in positioning and stabilising structures **3300** which are configured to support relatively heavy seal-forming structures such as full face or oro-nasal cushion assemblies.

The tubes **3350** in the form of the technology shown in FIG. **3**A have a length of between 15 and 30 cm, for example between 20 and 27 cm. In one embodiment the tubes are 25 cm long. The length of the tubes is selected to be appropriate to the dimensions of the heads of typical patients, for example the distance between the region proximate the top of the head where the upper end of the tubes **3350** are situated to the region proximate the openings to the patient's airways at which the lower end of the tubes **3350** connect to the cushion assembly **3150** when following a generally arcuate path down the sides of the heads and across the patient's cheek region such as is shown in FIG. **3**A. As described in more detail below, the patient interface **3000** is configured so that the length of the tubes **3350** can be varied in some forms of the technology and the above lengths may apply to the tube in a contracted, stretched or neutral state. It will be appreciated that the length of the tubes **3350** will depend on the length of other components in the patient interface **3000**, for example the length of arms of a T-shaped conduit to which the upper ends of tubes **3350** connect.

The level to which the patient interface **3000** fits an individual patient can be altered by varying the length of the tubes **3350** and, alternatively or additionally, by altering the position of the patient interface **3000** on the patient's head. For example, a patient interface **3000** having tubes **3350** of a certain length can be adjusted to better fit a patient by moving the positioning and stabilising structure **3300** in the posterior or anterior direction on the patient's head. Positioning the connection port **3600** further forward (i.e. in the anterior direction) enables a patient interface **3000** having tubes **3350** of a certain length to fit a larger head than if the connection port **3600** is positioned further backward (i.e. in the posterior direction).

In certain forms of the present technology the patient interface **3000** is configured such that the connection port **3600** can be positioned in a range of positions across the top of the patient's head so that the patient interface **3000** can be positioned as appropriate for the comfort or fit of an individual patient. One way this can be achieved so that the cushion assembly **3150** forms an effective seal with the patient's face irrespective of the position of the connection port **3600** on the patient's head is to de-couple movement of the upper portion of the patient interface **3000** from the lower portion of the patient interface **3000**. Such de-coupling can be achieved using, for example, mechanisms that allow parts of the headgear tubes **3350** to easily move or flex relative to other parts of the patient interface **3000**. Such mechanisms will be described below.

In a certain form of the present technology, the patient interface **3000** is configured such that the connection port **3600** is positioned approximately at a top point of the patient's head. The connection port **3600** may be positioned in the sagittal plane and aligned with the otobasion superior points in a plane parallel to the coronal plane. The otobasion superior points are identified in FIG. **2**D. As will be described below, in some forms of the technology, the headgear **3300** is configured to be worn in different positions, with the effect that the connection port **3600** may be positioned proximate the top of the patient's head in the sagittal plane up to around 20 mm forward or 20 mm rearward of the otobasion superior points.

The cross-sectional shape of the tubes **3350** may be circular, elliptical, oval, D-shaped or a rounded rectangle, for example as described in U.S. Pat. No. 6,044,844, the contents of which are incorporated herein. A cross-sectional shape that presents a flattened surface of tube on the side that faces and contacts the patient's face or other part of the head may be more comfortable to wear than, for example a tube with a circular cross-section.

The cross-sectional width and/or height of the tubes **3350** may be in the range 8-25 mm, for example 10-20 mm. In some forms in which the tubes have a D-shaped cross-section, for example in the case of the longitudinal section of headgear tubing **3350** shown in FIG. **3**H, the tubes have a width in the range 15-25 mm, for example 20 mm, and a height in the range 8-15 mm, for example 10 mm. The height may be considered to be the dimension of the tube away from the patient's face, i.e. the distance between the patient contacting side **3348** and the outermost part of the non-patient contacting side **3349**, while the width may be considered to be the dimension across the surface of the patient's head. The cross-sectional thickness of the material forming the tubes **3350** may be in the range 0.8-1.6 mm, for example 1.0-1.5 mm, for example 1.3 mm.

The D-shaped cross-sectional tube **3350** shown in FIG. **3**H has rounded edges **3347** flanking the patient contacting side **3348**. Rounded edges in contact with, or proximate to, the patient's skin help the patient interface **3000** to be more comfortable to wear and to avoid leaving marks on, or irritating, the patient's skin. A tube with a D-shaped cross-sectional profile is also more resistant to buckling than other shaped profiles.

Also as described in U.S. Pat. No. 6,044,844, the tubes **3350** may be crush resistant to avoid the flow of breathable gas through the tubes if either is crushed during use, for example if it is squashed between a patient's face and pillow. Crush resistant tubes may not be necessary in all cases as the pressurised gas in the tubes may act as a splint to prevent or at least restrict crushing of the tubes **3350** during use. A crush resistant tube may be advantageous where only a single tube **3350** is present as if the single tube becomes blocked during use the flow of gas would be restricted and therapy will stop or reduce in efficacy.

The two tubes **3350** are fluidly connected at their lower ends to the cushion assembly **3150**. In certain forms of the technology, the connection between the tubes **3350** and the cushion assembly **3150** is achieved by connection of two rigid components so that the patient can easily connect the two components together in a reliable manner. The tactile feedback of a 're-assuring click' or like sound may be easy for a patient to use or for a patient to know that the tube has been correctly connected to the cushion assembly **3150**. In one form, the tubes **3350** are formed from silicone and the lower ends of the silicone tubes **3350** are overmolded to a rigid connector made, for example, from polypropylene. The rigid connector may comprise a male mating feature configured to connect to a female mating feature on the cushion assembly **3150**, although the male/female features may be arranged the other way around.

In another embodiment a compression seal is used to connect the tube **3350** to the cushion assembly **3150**. For example, a resiliently flexible (e.g. silicone) tube **3350** without the rigid connector may need to be squeezed slightly to reduce its diameter so that it can be jammed into a port in the plenum chamber **3200** and the inherent resilience of the silicone pushes the tube **3350** outwards to seal the tube **3350** in the port in an air-tight manner. In a hard-to-hard type engagement between the tube **3350** and port, a pressure activated seal such as a peripheral sealing flange may be used. When pressurised gas is supplied through the tubes **3350** the sealing flange is urged against the join between the tubes and the inner circumferential surface of the port of the plenum chamber **3200** to enhance the seal between them. If the port is soft and a rigid connector is provided to the tube **3350**, the pressure activated seal as described earlier may also be used to ensure the connection is air-tight.

Similar connection mechanisms may be used to fluidly connect the tubes **3350** with a T-shaped top member defining the connection port **3600** or connectable to the connection port **3600** in some forms of the technology. In one embodiment, a swivel elbow connected at the connection port **3600** is rotatable in order to drive a port size adjustment mechanism that decreases or increases the size of the ports into which tubes **3350** are inserted in order to improve the fit of the tubes through an increase or decrease of compressive forces and to reduce unintended leakage.

8.3.3.2 Headgear Straps

In certain forms of the present technology, the positioning and stabilising structure **3300** comprises at least one headgear strap acting in addition to the tubes **3350** to position and stabilise the seal-forming structure **3100** to the entrance to the patient's airways.

8.3.3.2.1 Position of Headgear Straps

In one example, for example as shown in FIG. **3**A, the positioning and stabilising structure **3300** comprises a rear headgear strap **3310** connected between the two tubes **3350** positioned on each side of the patient's head and passing around the back of the patient's head, for example overlaying or lying inferior to the occipital bone of the patient's head in use. The rear strap **3310** connects to each tube above the patient's ears. In other embodiments, for example for an oro-nasal mask, the positioning and stabilising structure **3300** additionally comprises one or more lower side headgear straps that connect between the tubes and pass below the patient's ears and around the back of the patient's head.

In one form of the present technology, the positioning and stabilising structure **3300** comprises a chin strap **3320** that, in use, extends under the patient's chin, for example as shown in FIGS. **10**A and **10**B. The chin strap **3320** may be connected to the headgear tubes **3350** or, in another embodiment, to the cushion assembly **3150** or a frame assembly operatively connected to the cushion assembly.

Certain forms of the present technology may comprise multiple headgear straps to increase stability as described above, for example a rear strap, side headgear straps and a chin strap.

In certain forms of the technology, the positioning and stabilising structure **3300** comprises a mechanism for connecting a headgear strap to the seal-forming structure **3100**. The headgear strap may be connected directly or indirectly to the seal-forming structure **3100**. In the case of the patient interface **3000** shown in FIG. **3**A, for example, a tab **3345** configured to connect to rear strap **3310** projects outwardly from each headgear tube **3350** in a generally posterior direction. The tabs **3345** have holes in them to receive the ends of rear strap **3310**.

In some forms of the present technology, the rear strap **3310** is adjustable. For example, in the case of the patient interface shown in FIG. **3**C the rear strap **3310** is, in use, threaded through a hole in each tab **3345**. The length of the rear strap **3310** between the tabs **3345** may be adjusted by pulling more or less of the rear strap **3310** through one or both of the tabs **3345**. The rear strap **3310** may be secured to itself after passing through the holes in the tabs **3345**, for example, with hook-and-loop fastening means. The rear strap **3310** therefore is able to be adjusted to fit around different head sizes. In some forms of the technology the angle of the rear strap **3310** relative to the headgear tubes **3350** or patient's head is able to be adjusted to fit around the patient's head at a different locations. This adjustability assists the headgear **3300** to accommodate different head shapes and sizes.

In some forms of the technology, the rear strap **3345** exerts a force on the headgear tubes **3350** to pull them in an at least partially posterior (e.g. rearwards) direction at the locations of the tabs **3345**. The rear strap **3310** may also exert a force on the headgear tubes **3350** to pull them in an at least partially inferior (e.g. downwards) direction. The magnitude of this force may be adjusted by altering the length of the rear strap **3310** between the tabs **3345**.

In some forms of the technology, such as the form shown in FIG. **3**C, the direction of the force applied to the headgear tubes **3350** by the rear strap **3310** may also be altered. This direction may be altered by adjusting the angle of the rear strap **3310** relative to the headgear tubes **3350** or patient's head. In some forms of the technology the location at which the rear strap **3310** exerts a force on the headgear tubes **3350** may be altered by adjusting the location at which the rear strap **3310** is secured to the headgear tubes **3350**.

The adjustability of the magnitude and direction of the force applied to the headgear tubes **3350** by the rear strap **3310** may advantageously enable the headgear **3300** to accommodate a range of head sizes and head shapes. The rear strap **3310** may balance forces in the headgear tubes **3350** which may assist the headgear to maintain its shape and an effective seal to the patient's face, while remaining comfortable.

In some forms of the technology, when worn by a patient, a point on the headgear tubes **3350** near the tab **3345** will receive a generally upward (e.g. superior) force from the upper portion of the headgear tubes **3350** due to a biasing mechanism (described in further detail below) acting to keep the headgear secured to the patient's head. Additionally, the point on the headgear tubes **3350** near the tab **3345** may receive a generally forward (e.g. anterior) and downward (e.g. inferior) force caused by a biasing mechanism acting to urge the seal forming structure **3150** upwards and into the patient's nose. The directions and magnitudes of the forces required for a secure fit and effective seal may vary between patients based on the position of the positioning and stabilising structure **3300** on the head, which may vary due to, for example, differences in head shapes and sizes. In some forms of the technology, the adjustability of the rear strap **3310** enables the forces to be balanced for a range of head shapes and sizes to hold the headgear **3300** in a comfortable position while maintaining an effective seal.

For example, to balance a large force acting in the anterior (e.g. forward) direction on the portions of the headgear tubes **3350** proximate the tabs **3345**, the rear strap **3310** may be adjusted by pulling more of the rear strap **3310** through the slots in the tabs **3345**, thereby causing the rear strap **3310** to shorten in length and, if the rear strap **3310** is elastic, to apply a larger force on the headgear tubes **3350** in the posterior (e.g. rearward) direction. Similarly, the angle of the rear strap **3310** may be adjusted as required to balance both the vertical and horizontal components of the forces acting on the portions of the headgear tubes **3350** proximate the tabs **3345**, across a range of head shapes and sizes.

8.3.3.2.2 Form of Headgear Straps

In one example, the positioning and stabilising structure **3300** comprises at least one strap **3310** having a rectangular cross-section. In one example the positioning and stabilising structure **3300** comprises at least one flat strap. In another example the positioning and stabilising structure **3300** comprises at least one strap **3310** having a profile with one or more rounded edges to provide greater comfort and to reduce the risk of headgear straps marking or irritating the patient.

In one form of the present technology, a positioning and stabilising structure **3300** comprises a strap **3310** constructed from a laminate of a fabric patient-contacting layer, a foam inner layer and a fabric outer layer. In one form, the foam is porous to allow moisture, (e.g., sweat), to pass through the strap **3310**. In one form, the fabric outer layer comprises loop material to engage with a hook material portion. The hook material portion may be positioned at a distal portion of the strap **3310**.

In certain forms of the present technology, a positioning and stabilising structure **3300** comprises a strap **3310** that is extensible, e.g. resiliently extensible. For example the strap **3310** may be configured in use to be in tension, and to direct a force to draw the seal-forming structure **3100** into sealing contact with a portion of a patient's face. In an example the strap may be configured as a tie. In other forms of the technology, the positioning and stabilising structure **3300** comprises a strap **3310** that is adjustable in order to alter the length of the strap. For example, the strap **3310** may connect to tubes **3350** by a strap adjustment mechanism, e.g. hook-and-loop fasteners. An adjustable strap **3310** may add further adjustment capability to other adjustment features of the patient interface **3000** to enable a patient to improve comfort and fit. In some forms of the present technology the degree of adjustability provided by other parts of the positioning and stabilising structure may mean the patient interface **3000** is sufficiently adjustable without strap **3310** also being adjustable.

In certain forms of the present technology, a positioning and stabilising structure **3300** comprises a strap **3310** that is bendable and e.g. non-rigid. An advantage of this aspect is that the strap **3310** is more comfortable for a patient to lie upon while the patient is sleeping.

In certain forms of the present technology, a positioning and stabilising structure **3300** comprises a strap **3310** that comprises two or more strap bands separate by a split. A split strap **3310** may anchor the patient interface **3000** on the patient's head in a particularly stable fashion in the case of some patient interface designs.

In certain forms of the present technology, a positioning and stabilizing structure **3300** provides a retaining force configured to correspond to a particular size of head and/or shape of face. For example one form of positioning and stabilizing structure **3300** provides a retaining force suitable for a large sized head, but not a small sized head. In another example, a form of positioning and stabilizing structure **3300** provides a retaining force suitable for a small sized head, but not a large sized head.

8.3.3.3 Headgear Tubing Adjustment Mechanism

In certain forms of the present technology, the positioning and stabilising structure **3300** comprises an adjustment mechanism **3360**. Adjustment mechanism **3360** is configured to allow the positioning and stabilising structure **3300** to be dimensionally adjusted. In at least one embodiment, the adjustment mechanism **3360** may particularly allow length adjustment of the positioning and stabilising structure **3300** between the connection port **3600** and seal-forming structure **3100**, for example length adjustment of a tie, for example the headgear tubing **3350**. Additionally or alternatively, the adjustment mechanism **3360** is configured to enable the positioning and stabilising structure **3300** to be bendably adjusted, for example bending of the headgear tubing **3350**. The adjustment mechanism **3360** allows the patient interface **3000** to be adjusted to improve the fit of the patient interface **3000** to the patient's head, and thereby to enable the patient interface **3000** to fit different size heads. A patient interface that fits a patient well is comfortable to wear, is likely to be more stable and thus reduces the likelihood of seal disruption and maintains the sealing structure against the entrance of the patient's airways with a comfortable level of headgear tension. These factors improve patient compliance with therapy, improving therapeutic results. It will be understood that the adjustment mechanism may comprise a plurality of mechanisms for adjustment. For example, combinations of adjustment mechanisms described below may be provided to headgear in some forms of the present technology.

For example, the adjustment mechanism **3360** may allow the size and/or shape of the patient interface **3000** to be adjusted. In one form of the technology, the length of tubes **3350** between the connection port **3600** and the seal-forming structure **3100** may be adjusted.

In some forms of the technology, the adjustment mechanism **3360** allows the size of the patient interface **3000** to be adjusted by a total of up to 100 mm to allow the patient interface **3000** to fit a broad range of patients. For example, the adjustment mechanism **3360** may allow the total length of the tubes **3350** to be adjusted by a total of up to 100 mm. In one form of the technology, the total length of the tubes **3350** can be adjusted by a total of up to 80 mm. For example, the length of the tube **3350** positioned on each side of the patient's face in use may be adjusted by up to 40 mm.

The patient interface **3000** may be configured and structured so that, if the positioning and stabilising structure **3300** exerts a force on the patient's face to retain the cushion assembly **3150** in sealing relationship with the patient's face against the force exerted by the gas at positive pressure inside the plenum chamber **3200**, that force is approximately constant or within predetermined limits over the range of sizes the patient interface **3000** is able to adopt. This is described in more detail below.

Different forms of adjustment mechanisms **3360** will be described in the ensuing description. In some forms the adjustment mechanism **3360** is comprised as part of the headgear tubing **3350** while in other forms the adjustment mechanism **3360** is distinct from the headgear tubing **3350**. Certain forms of the technology may comprise multiple adjustment mechanisms **3360** as described below.

In some forms of the technology the adjustment mechanism **3360** is configured to be manually adjusted to enable the patient interface **3000** to fit the patient comfortably and with therapeutic effectiveness, i.e. adjusted by the patient or other person. In other forms the adjustment mechanism **3360** is configured to automatically adjust to fit the patient. An automatic adjustment mechanism may provide an advantage in that it reduces the chances of a patient fitting the patient interface **3000** incorrectly or uncomfortably. On the other hand, some patients may prefer the ability to alter the fit of the patient interface themselves.

In some forms of the technology, the patient interface **3000** is configured such that different forms of seal-forming structure **3100** can be interchangeably connected to the positioning and stabilising structure **3300**. The different forms of seal-forming structure **3100** may include seal-forming structures of different size and weight. For example, an oro-nasal cushion may be heavier than a nasal cushion. In such forms of the technology a manual adjustment mechanism may provide an advantage in that the mechanism can be initially set to suit the type of seal-forming structure being used. For example, the manual adjustment mechanism may be set to provide a tighter fit if a relatively heavy seal-forming structure is used to counteract the tendency of a relatively heavy seal-forming structure to pull on the positioning and stabilising structure **3100** in an inferior direction. Similar considerations may apply to seal-forming structures that are subject to movement by a patient's mouth (e.g. jaw drop).

8.3.3.3.1 Folding/Concertina Headgear Tubes

In certain forms of the technology, the adjustment mechanism **3360** comprises tubes **3350** having one or more folding portions, pleats, corrugations or bellows, i.e. the folding portions pleats, corrugations or bellows comprise the adjustment mechanism **3360**. When each folding portion is in a first, folded configuration, the length of the respective tube **3350** is different to its length when the folding portion is in a second, unfolded configuration.

The patient interface **3000** shown in FIG. **3**A comprises tubes **3350** comprising a concertina tube section **3362** between lengths of the tubes **3350** without concertinas. Concertina tube section **3362** comprises a plurality of folds or bellows able to fold and unfold independently or in concert to shorten or lengthen the concertina tube section **3362** and hence the respective tube **3350**. The folds in concertina tube section **3362** may be able to be expanded (stretched) or contracted by differing degrees on different sides of the tube **3350**. For example, the concertina folds on the side of the tube **3350** nearest the patient's head may be contracted more than those furthest from the patient's head, which increases the curvature of the tubes **3350**. This allows the shape of the tubes **3350** to be altered as well as their length, which also helps the patient interface be adjusted to fit the patient's specific head size and head shape.

In certain forms of the technology the concertina tube sections **3362** provide for adjustment of the length of the tubes **3350** of the patient interface **3000** continuously through a range of different lengths. In some embodiments the length of each concertina tube section may be continuously adjustable. An adjustment mechanism, such as a concertina section, which provides for continuous adjustment may fit comfortably to a wide range of head sizes. In contrast, an adjustment mechanism which provides of adjustment between discrete lengths may fit less comfortably on a patient for whom the most comfortable fit would require a length between two of the discrete length options.

In some forms of the technology the tubes **3350** comprise a plurality of concertina tube sections **3362** at predetermined locations, each separated by lengths of the tubes **3350** without concertinas.

In some forms of the technology, concertina tube sections **3350** are situated in relatively straight portions of the tubes **3350**. This avoids the tendency for concertina sections **3350** to straighten when pressurised gas is passed through the tubes **3350**, which may alter the position of the patient interface on the patient's head and adversely affect the stability of the seal and/or flow impedance.

In the form of the technology shown in FIG. **3**B, patient interface **3000** comprises tubes **3350** comprising concertina tube sections **3362** that are longer than the concertina tube sections **3362** shown in FIG. **3**A. In the form of the technology shown in FIG. **3**B the concertina tube sections **3362** span the majority of the length of the respective tube **3350** in between the point at which headgear strap **3310** connects to the tube **3350** and the upper end of the tube **3350** that connects to connection port **3600**. For example, the concertina tube sections **3362** may have a lower end at a point just above the point at which headgear strap **3310** connects to the tube **3350** and may have an upper end at the point where tube **3350** connects to connection port **3600**. A longer concertina tube section may provide a greater extensibility to the tube **3350**. A high extensibility may alternatively be provided by increasing the number of concertina folds in the concertina tube section **3362**. A greater extensibility may be advantageous in enabling the patient interface **3000** to fit many patients with a large range of head sizes while exerting a desired level of retaining force on a patient's face to ensure a good seal across this range of head sizes.

In the form of the technology shown in FIGS. **3**C, **3**D and **3**E the patient interface **3000** is similar to the patient interface **3000** shown in FIG. **3**B. One difference is the configuration of the concertina tube sections **3362**. In the form of the technology shown in FIGS. **3**C, **3**D and **3**E, the concertina tube sections **3362** have a width and diameter that vary along the length of each concertina tube section **3362**. More particularly, the concertina tube sections **3362** taper so that the width and diameter of the tube at one end of each concertina tube section **3362** is smaller than the width and diameter of the tube at the other end of each concertina tube section **3362**. More particularly still, the upper end of each concertina tube section **3362** (where the concertina tube section **3362** connects to connection port **3600**) has a larger width and diameter than the lower end of each concertina tube section **3362** (where the concertina tube section **3362** connects to a section of tube **3350** without concertinas), with the width and diameter of the concertina tube section **3362** increasing gradually and approximately linearly in between the upper and lower ends. The tapering of the concertina tube section **3362** is also shown in FIG. **3**F, which shows in plan view the patient interface **3000** of FIGS. **3**C, **3**D and **3**E, and FIG. **3**G, which shows the patient interface **3000** of FIG. **3**F in cross-section along the line **3**G-**3**G. The tapering of the concertina tube section **3362** fluidly connects the connection port **3600** to the lower lengths of tubes **3350** without concertinas in a manner that reduces discontinuities in the cross-sectional profile of the air path, providing a smooth transition to reduce added impedance and promote fluid flow along the tubes **3350**.

One advantage of concertina tube sections **3362** for the adjustment mechanism **3360** is that concertina tube sections may be more readily able to curve or bend as well as extend longitudinally, in comparison to other adjustment mechanisms. FIG. **3**J shows headgear **3300** worn in three different positions on a patient's head indicated by reference numerals with suffixes "a", "b" and "c". As shown in FIG. **3**J, the concertina tube sections **3362***a, b* and *c* are curved to different extents with concertina tube section **3362***a* curving forwardly on the patient's head, concertina tube section **3362***b* having less curvature in the posterior/anterior direction and concertina tube section **3362***c* having substantially no curvature on the patient's head.

In some forms of the technology, the concertina tube sections **3362** are able to extend by different amounts on the front and rear (e.g. anterior and posterior) sides of the headgear tubes **3350**. That is, the walls forming the concertina tube sections **3362** may be relatively more contracted (e.g. more folded) on one side of the tube, and relatively more extended (e.g. unfolded) on the opposite side of the tube, to facilitate a bend or curve in the tube. This effect is visible in FIG. **3**L. As shown, the walls of the concertina tube section **3362** are less extended (e.g. more collapsed) on the anterior side than on the posterior side in the case of concertina tube section **3362***a*, i.e. when the headgear is worn on the patient's head forwardly of the coronal plane. The ability for the concertina tube sections **3362** to curve in the anterior direction helps enable the headgear **3300** to be worn in a forward position without causing the cushion assembly **3150** to roll forward and out of sealing contact with the patient's face, which may occur if the headgear tubes were rigid. The ability for the headgear tubes **3350** to curve in anterior or posterior directions assists in decoupling the connection port **3600** from the cushion assembly **3150**. There is less difference in the amount of extension of the concertina tube section **3362***c* between the front and rear sides of the concertina tube section **3362***c* (i.e. when the headgear **3300** is worn in a rearward position on the patient's head) compared to the difference in the amount of extension of the concertina tube section **3362***a* between the front and rear sides of the concertina tube section **3362***a* (i.e. when the headgear **3300** is worn in a forward position on the patient's head). The concertina enables the headgear tubes **3350** to straighten (or curve) less in order to be worn rearwardly.

In one form, the concertina tube sections **3362** on each side of the patient interface **3000** are approximately 40 mm longer in a fully expanded configuration compared to a fully contracted configuration.

In other forms of the technology, the concertina tube sections **3362** may be situated at a different portion of the length of tubes **3350**. One advantage of the patient interfaces **3000** shown in FIGS. **3**A and **3**B, in which the concertina tube sections **3362** are located at a position along the length of the tubes **3350** so that the concertina tube sections **3362** are in contact with the top and/or upper sides of the patient's head, i.e. a region of the patient's head superior to the otobasion superior of the patient's head, is that the concertina tube sections **3362** are not in contact with the patient's cheek region. This avoids the discomfort that might arise if a concertina tube section contacted a patient's cheek region in use.

The concertina tube sections **3362** may be vulnerable to collapsing, particularly when they are heavily stretched. This presents a risk that the concertina tube sections **3362** cause a blockage in tubes **3350** which restricts or prevents the delivery of breathable gas to the patient. In some forms of the technology, the patient interface **3000** comprises one or more structures configured to prevent or at least hinder collapsing of the concertina tube sections **3362**. In one embodiment, the patient interface **3000** comprises one or more rigid or semi-rigid rings provided to the concertina tube sections **3362** and positioned circumferentially around the tubes **3350**. For example, the rings may be placed inside the concertina tube sections **3362** or they may be moulded (for example co-moulded or overmoulded) with the concertina tube sections **3362**. In another embodiment a helical element is provided along the concertina tube sections **3362** to hinder collapse. In such an embodiment, the sections of material between the pitch of each helix turn, known as the tape, may provide resiliency to the tube. The tape may be formed of a resilient material or otherwise be structured to provide the appropriate level of elasticity to exert sufficient tension forces on the tube for contraction. In other embodiments, the concertina tube sections **3362** are formed with concertina tube sub-sections having a higher thickness or being made of a stiffer material than other concertina tube sub-sections such that collapse is hindered.

In another form of the technology, the patient interface comprises an adjustment mechanism **3360** comprising tubes **3350** having one or more circumferential folds enabling adjacent sections of the tubes **3350** to fold longitudinally. When the circumferential folds are in a folded configuration, a length of the tube overlays an adjacent length of tube. The rigidity of the material from which the tubes are formed may be configured so that the tubes tend to stay in the folded configuration unless pulled apart by a substantial force (greater than, for example, a force exerted on the tubes during typical use of the patient interface). Alternatively, the patient interface may comprise means to maintain the tubes in a folded configuration, for example clips. In another embodiment, magnets are embedded in the tube that align between overlaying folding portions when the tube is folded to maintain the tube in a folded configuration unless the magnets are pulled apart.

The patient interface **3000** shown in FIG. **5** comprises an adjustment mechanism **3360** comprising a fold portion **3364**. Fold portion **3364** comprises a first tube wall portion **3366** able to fold over an adjacent tube portion **3368** by a varying degree by rolling over the adjacent tube portion. FIGS. **5**A and **5**B are cross-sectional views of the fold portion **3364** of the patient interface **3000** shown in FIG. **5**. In FIG. **5**A the rolling fold portion **3366** is folded over adjacent tube portion **3368** to a greater degree than how much it is folded over in FIG. **5**B and therefore the length of the tube **3350** when the fold portion **3364** is in the configuration shown in FIG. **5**B is longer than the length of the tube **3350** when the fold portion **3364** is in the configuration shown in FIG. **5**A. It can be seen from FIGS. **5**A and **5**B that, at the location of the fold portion **3364**, three layers of tube **3350** overlap each other, although the length of the overlapping tube sections differs between the configuration of FIG. **5**A compared to the configuration of FIG. **5**B. The rolling fold portion **3366** may comprise a localised section of tube wall that is thinner than other sections of the tube **3350**.

Another form of folding adjustment mechanism **3360** for a positioning and stabilising structure **3300** of a patient interface **3000** is shown in FIG. **6**. In this embodiment of the present technology, tubes **3350** extend from a connection port **3600** to tube ends **3352** which are configured to connect to a cushion assembly **3150** of the patient interface **3000**. Tubes **3350** have a generally wavy shape along their length and comprises at least one curved portion, for example curved portions **3353**A, **3353**B. The tubes **3350** are formed of a material that has sufficient flexibility for the curved portions to increase in curvature or decrease in curvature to allow each tube to fit a smaller or larger head respectively. For example, the tubes may be formed of meta-silicon having a hardness of 40 durometer on the Shore hardness scale.

In the form of the technology shown in FIG. **6**, a tube **3350** on one side of the patient's head extends, at an upper end, in a generally anterior-inferior direction away from the connection port **3600** and a generally inferior direction at the side of the patient's head proximate the point that headgear strap **3310** attaches to the tube **3350** such that there is an upper curved portion **3353**A positioned generally over an upper side portion of the patient's head and having the outer part of the curved portion on the anterior side and the inner part of the curved portion on the posterior side. Below the point that headgear strap **3310** attaches to the tube **3350**, the tube **3350** extends generally in the inferior direction and curves slightly forwards in the anterior direction. A lower curved portion **3353**B is positioned in use generally above the patient's cheek region. A lower end of tube **3350** extends across the patient's cheek generally horizontally in the anterior direction towards tube ends **3352** which connect to cushion assembly **3150**. The lower end of tube **3350** may be oriented slightly downwards, i.e. extending slightly in the inferior direction, when worn by some patients. The lower curved portion **3353**B positioned generally over the patient's cheek region has the outer part of the curved portion on the posterior side and the inner part of the curved portion on the anterior side.

The lower portion of tube **3350** in FIG. **6** is structured and configured so that the tube **3350** is generally positioned, in use, away from the patient's eyes so that the tube **3350** does not enter into the patient's field of view, or at least does so minimally. This may be achieved by structuring the lower portion of tube **3350** so that the apex or the point of maximum curvature of lower curved portion **3353**B is positioned in use over a rear region of the patient's cheek region.

Although not shown in FIG. **6**, the tube **3350** positioned over the left side of the patient's face is structured symmetrically to the tube **3350** over the right side of the patient's face. In other forms, the tubes **3350** may have different structures on each side of the patient's face.

8.3.3.3.2 Telescopic Headgear Tubes

In certain forms of the technology, the adjustment mechanism **3360** comprises tubes **3350** having a first tube portion **3370** that is telescopically moveable relative to a second tube portion **3372**.

The patient interface **3000** shown in FIG. **7**A comprises an adjustment mechanism **3360** comprising first and second tube portions **3370** and **3372** that slide telescopically relative to each other. In the embodiment of FIG. **7**A, first tube portion **3370** is connected to the connection port **3600** and is therefore positioned higher on the patient's head than the first tube portion when the patient interface is worn. The second tube portion **3372** has a smaller diameter than, i.e. fits inside, first tube portion **3370** and is fixedly connected to a part of the tube **3350** positioned lower on the patient's head when the patient interface is worn. First tube portion **3370** may be described as enveloping second tube portion **3372** through the telescopic movement between the two tube portions.

In certain forms of the present technology, the patient interface comprises a tube securing mechanism that secures the first and second tube portions **3370** and **3372** in a plurality of discrete positions relative to one another. For example, in the form of the technology shown in FIG. **7**A, second tube portion **3372** comprises a plurality of raised ribs **3374** on an outer surface and first tube portion **3370** comprises one or more protrusions or detents (not shown) that interlock with the ribs **3374** to hold the first and second tube portions **3370** and **3372** in a plurality of relative longitudinal positions, enabling the length of the tubes **3350** to be adjusted. In other forms of the technology, the tube sections may be secured in a plurality of discrete positions using other interlocking mechanisms, for example one or more grooves or holes that interlock with one or more protrusions or detents. It will be appreciated that the grooves may be provided on a surface of either the first or second tube portions with the protrusions provided on a surface of the other of the first or second tube portion in a position to interlock with the grooves in use.

In one form, the patient interface **3000** of FIG. **7**B comprises an adjustment mechanism **3360** comprising first and second tube portions **3370** and **3372** that slide telescopically relative to each other. The first tube portion **3370** may slide over the outer surface of the second tube portion **3372**. The second tube portion **3372** is positioned lower on the patient's head when patient interface **3000** is worn than first tube portion **3370**, i.e. second tube portion **3372** is downstream of first tube portion **3370**. The patient interface **3000** has two similar such adjustment mechanisms **3360**, one positioned on each side of the patient's head in use.

Patient interface **3000** comprises an upper tube member **3351** which is positioned over the top portion of the patient's head in use. First tube portions **3370** on each side of the patient's head are integrally formed as part of upper tube member **3351**. A connection port **3600** is provided to upper tube member **3351**, for example the upper tube member **3351** has an opening in an upper side of the central portion thereof.

The first tube section **3370** on each side of the patient's head may comprise a first or upper tab **3371** and the second tube portion **3372** may comprise a second or lower tab **3373**. The second tab **3373** may be pushed towards the first tab **3371**. For example, the user may place their thumb on the second tab **3373** and their index finger on the first tab **3371** and pinch the two tabs together such that the second tab **3373** moves towards the first tab **3371**. Moving the second tab **3373** towards the first tab **3371** telescopically slides the first and second tube portions **3370** and **3372** to shorten the headgear tubes **3350**. Moving the second tab **3373** away from the first tab **3371** telescopically slides the first and second tube portions **3370** and **3372** to lengthen the headgear tubes **3350**.

The second tab **3373** may slide towards a peripheral edge of the first tube **3370** such that when the second tab **3373** contacts the peripheral edge it acts as a stop to prevent further shortening of the tube **3350**.

The second tube portions **3372** of the patient interface **3000** shown in FIG. **7**B are integrally formed with the lengths of tube **3350** that, in use, are positioned in contact with the side of the patient's head and across the patient's cheek region. So that the patient interface **3000** is comfortable to wear and able to adapt to the shape of a range of patients' heads, the lower parts of tubes **3350** (of which second tube portions **3370** are an integral part) may be formed of a semi-rigid material such as an elastomeric material, e.g. silicone. In contrast, upper tube member **3351** (and consequently first tube portions **3370**) may be formed from a relatively rigid material.

One possible consequence of a patient interface in which a tube portion formed from a relatively flexible material telescopically moves relative to a tube portion formed from a relatively rigid material is that, when the inner tube portion is pushed towards the outer tube portion, the tube portion made of the relatively flexible material may buckle. This may affect the ease with which the length of tubes **3350** can be adjusted. The patient interface **3000** shown in FIG. **7**B comprises rigidising members **3379** to address this problem. Rigidising members **3379** act to increase the rigidity of the section of second tube portion **3372** that moves, in use, in and out of first tube portion **3370**. In the embodiment shown, rigidising members **3379** are lengths of relatively rigid material provided to the upper side of each of second tube portions **3372**. The rigidising members **3379** may be mounted on the outer side of the second tube portions **3372** or they may be moulded (for example co-moulded or overmoulded) as part of second tube portions **3372**. In certain forms of the technology, each rigidising member **3379** may be integrally formed with the tab **3373** on an upper side of the tab **3373** on the respective second tube portion **3372**.

The patient interface of FIG. **7**B comprises a padded member **3330** on a patient contacting side of the upper tube member **3351** to improve comfort when the patient interface **3000** is worn. One or more padded members **3330** may be provided to any part of the positioning and stabilising structure **3300** of any of the forms of patient interface **3000** described in this specification unless otherwise stated. For example, padded members **3330** may be provided to a part of the tubes **3350** to make wearing the patient interface more comfortable. Padded members **3330** may be permanently attached to a part of tubes **3350**, for example by being moulded (e.g. co-moulded or overmoulded) or adhered thereto. Alternatively, padded members **3330** may be removably attached to tubes **3350**, for example using hook-and-loop fastening material or fasteners. Since padded members **3330** will, in use, be in contact with the patient's head, they may become dirty and the ability to remove them for cleaning and/or replacement may be advantageous.

Another form the present technology is illustrated in FIG. **7**C. In this form, patient interface **3000** comprises a second tube portion **3372** that telescopically slides over the outer surface of the first tube portion **3370**. That is, the tube portion telescopically fitting inside the other tube portion is positioned higher than the other tube portion on the patient's head in use.

In the embodiment of FIG. **7**C, first tube portion **3370** is relatively rigid. Second tube portion **3372** comprises a relatively rigid ring member **3384** at its upper end. Ring member **3384** encircles the opening in the upper end of the second tube portion **3372**. Second tab **3373** may be provided to, for example integrally formed with, ring member **3384**. Since first and second tube portions **3370** and **3372** are both formed of relatively rigid materials, they are able to telescopically move relative to each other without buckling. The patient interface **3000** shown in FIG. **7**C may therefore avoid the need for a rigidising member such as is described in relation to FIG. **7**B while still allowing the same length of extension of the tubes **3350**.

Another form of telescopic adjustment of tubes **3350** is shown in FIG. **8**. In this embodiment, a second tube portion **3372** of tubes **3350** telescopically slides relative to a first tube portion **3370** with a ratchet mechanism **3376**. Ratchet mechanism prevents or hinders movement of the telescopically moveable first and second tube portions relative to each other in one or both directions unless the ratchet mechanism is released, for example by pushing buttons **3378**. Buttons **3378** are each operatively connected to a locking member (not shown) that interlocks with grooves or protrusions (e.g. ribs **3374**) on second tube portion **3372** unless button **3378** is pushed down.

Another form of ratchet mechanism **3376** is shown in the form of the technology shown in FIG. **7**C. In this form, ratchet mechanism **3376** comprises a tongue **3397** provided to the head contacting side of second tube portion **3372**. Tongue **3397** is connected to second tube portion **3372** at a lower end and extends generally along the length of second tube portion **3372**. Tongue **3397** is free at its upper end and has a protrusion on its upper side. First tube portion **3370** comprises a plurality of grooves **3398** on its head contacting side. The protrusion on the end of tongue **3397** is configured to selectively mate with each of grooves **3398** in order to hold the first and second tube portions **3370**, **3372** in relative position. Tubes **3350** may have a generally D-shaped cross-section with the flat part of the 'D' contacting the patient. Ratchet mechanism **3376** may be advantageously located on the head contacting side of the patient interface **3000** (such as is the case in FIG. **7**C) as tongue-and-groove ratchet mechanism **3376** may be more effective if provided on a relatively flat region of tube **3350** to provide a larger contact area than that which would result if more curved surfaces mated in the ratchet mechanism.

In an alternative form of the technology, button **3378** comprises tabs positioned on the sides of tube **3350** that are squeezed inwardly to release an interlock mechanism and allow the telescoping tube sections to be moved relative to each other. The tabs may comprise a gap or window in the first tube section **3370**, which envelopes the second tube section **3372**, enabling a patient or clinician to squeeze together a section of the second tube section **3372** to release the interlock. Alternatively, the gap may be covered by one or more overmoulded buttons which are pressed to squeeze on the second tube section **3372** to release the interlock. Covering the gap with overmoulded buttons or otherwise avoiding gaps in the adjustment mechanism **3360** reduces the prospect of the patient's hairs being caught in the adjustment mechanism **3360**, which may reduce comfort. In one exemplary embodiment, the adjustment mechanism **3360** is configured such that, when the sides of ring members **3384** at the upper end of the second tube portions **3372** are pressed inwardly, interlocking features between the second tube portions **3372** and first tube portions **3370** are released and telescopic movement between the tube portions is possible. For example, the ring member **3384** may comprise a silicone overmoulded hard plastic pinch button and one or more protrusions on its inner top surface to interlock with grooves on the top surface of the first tube portion **3370** so that, when the ring member **3384** is squeezed inwardly at the sides, the protrusions and grooves are pushed out of interlocking engagement.

The patient interface of FIG. **8** comprises padded members **3330** on a patient contacting side of the positioning and stabilising structure **3300** to improve comfort when the patient interface **3000** is worn.

Another form of telescopic adjustment of tubes **3350** is shown in FIG. **9**. In this embodiment the tube **3350** comprises a plurality of nested concentric tube sections **3375***a*, **3375***b* and **3375***c* that slide relative to each other. Each nested concentric tube section **3375** can be fully exposed or fully covered by telescopically extending or retracting an adjacent nested concentric tube section **3375** relative to it with the nested concentric tube sections interlocking with one another in fully extended or contracted positioned to hold their position, for example via a snap-fit mechanism. In some embodiments, the nested concentric tube sections **3375** can be held in intermediate positions, i.e. not fully extended or retracted.

In the embodiment shown in FIG. **9**, each nested concentric tube section is marked with a visual indicator **3377** representative of the length of the tube **3350** if that tube section is exposed, for example 'S' for small **3377***a*, 'M' for medium **3377***b* and 'L' for large **3377***c*. Other forms of indicator may also be used, for example numerical indicators or coloured indicators. Physical indicators may also be used such as embossment which may be advantageous in dimly lit rooms prior to the patient sleeping. The nested concentric tube sections **3375***a-c* may be configured to extend or retract in a predetermined order.

Other forms of the technology comprise tubes **3350** formed from multiple telescoping tube sections that are coupled together in other ways. For example, each tube **3350** may comprise a central inner tube section flanked by two outer tube sections, the central inner tube section telescopically sliding in and out of each of the two outer tube sections in use. Alternatively, the central tube section may be outside the two outer tube sections.

In other forms of telescopically adjustable headgear tubes forms of other size indicators may be provided. In certain forms, a first tube section **3370** of a tube **3350** that envelopes a second tube section **3372** during telescopic movement between the two tube sections may comprise a window or gap through which a visual indicator **3377** on the second tube section **3372** can be seen to indicate the size of tube **3350** thus provided.

Another telescopic adjustment mechanism **3360** for headgear tubes **3350** is shown in FIG. **10**A. In this embodiment the length of the headgear tubes **3350** is able to be adjusted by an adjustment mechanism **3360** comprising a cog or pinion **3383** that, when rotated, causes ribbed or racked portions of adjacent first and second tube sections **3370** and **3372** of tube **3350** to move telescopically, thus altering the length of the tube **3350**. The first tube section **3370** may be integrally, permanently or removably connected to cushion assembly **3150**. In the embodiment shown in FIG. **10**A the adjustment mechanism **3360** is positioned at a lower end of the headgear tubes **3350**. For example, adjustment mechanism **3360** may be provided in or adjacent to the cushion assembly **3150**. In the embodiment shown in FIG. **10**A, rotation of the cog or pinion **3383** causes the lower end of tube **3350** to move telescopically in relation to the cushion assembly **3150**.

In another form of the technology the adjustment mechanism **3360** is located at the connection port **3600** and a swivel elbow is provided to the cog or pinion so that rotation of the elbow causes movement of headgear tube sections relative to each other or relative to a T-shaped connection port member. A lock may be provided to prevent or limit rotation of the elbow when the desired arrangement is achieved.

Where a discrete number of relative positions of first and second tube sections is provided for by the telescopic adjustment mechanism it will be appreciated that a higher number of positions allows for more adjustment positions and promotes a better fit for patients. In some embodiments, 3, 4, 5, 6 or more adjustment positions are provided.

In certain forms of the technology, telescoping tube sections are configured to move relative to each other and be adjusted in a continuous fashion, i.e. the relative position of the tube sections is not constrained to discrete positions. This enables a greater degree of customisation in the length of the tubes **3350**.

One example of a tube **3350** having a continuously adjustable length is shown in FIG. **10**B in which tube section **3372** comprises a first threaded portion **3382** on first tube section **3370** which is in screwed engagement with a second threaded portion **3380** on second tube section **3372**. Rotation of one of the threaded portions relative to the other adjusts the length of tube **3350** by translating the rotational movement into relative longitudinal movement of the associated tube sections. One or both of the threaded portions are connected in rotational engagement to the other parts of their respective tube portions so that rotation of the threaded portions does not twist the rest of the tube **3350**. The enveloped or smaller diameter first threaded portion **3372** may be provided on the lower end of the tube **3350**, i.e. the part of tube **3350** connected to cushion assembly **3150** (as shown in FIG. **10**B) or to the upper end of the tube **3350**, i.e. the part of tube **3350** connected to the connection port **3600**. An abutment or screw-limiting member (not shown) may be provided at one end of one of the threaded sections to prevent the threaded sections being screwed apart and detached accidently during use.

In one form of the technology, a screw mechanism is provided as a fine adjustment mechanism in addition to a coarser adjustment mechanism, which may be any of the other adjustment mechanisms described herein, for example. In general any of the adjustment mechanisms described herein may be used in combination, with a first adjustment mechanism providing a finer adjustment than a second adjustment mechanism.

In another embodiment of the present technology, telescoping sliding sections of tube **3350** are held in frictional contact through ribs on the sliding surface of one or both sliding sections. Alternatively, one or more O-rings may be provided between the telescopically sliding tube sections. The ribs or O-rings hold the tube sections together with sufficient frictional force to keep them in the desired position during normal use of the patient interface but enable their relative position to be adjusted on application or a sufficient longitudinal adjustment force.

In another form of the technology, telescopic tube sections may be secured in position using other securing mechanisms. In one example, a length of a strap is attached to one of the telescopic tube sections with a portion of hook-and-loop fastener material provided to the strap. The strap may be secured to a complimentary portion of hook-and-loop fastener material provided to the other telescopic tube section to secure the sections in the desired position and thereby effect adjustment of the length of tube **3350**.

In the above-described embodiments of the present technology in which one or more tube sections are telescopically movable relative to other tube sections it will be appreciated that the tube sections are telescopically engaged in a substantially sealed manner to reduce the amount of breathable gas leaking from the patient interface. The manner in which this is achieved will differ depending on the nature of the telescopic engagement but one or more O-rings or other sealing members may typically be provided.

In the case of the patient interface **3000** shown in FIG. **7**B, for example, an O-ring is provided on an inner surface of the lower end of first tube portion **3370**. For example, the O-ring may be provided in a slot on the inner surface of the lower end of first tube portion **3370**. The O-ring is in sealing contact with the outer surface of the upper end of second tube portion **3372**. In other forms of the technology, the O-ring may be provided on the outer surface of the upper end of second tube portion **3372**. In one example, the O-ring is provided to, or is integrally formed with, the rigidising member **3379**.

The configuration and structure of the sealing contact between the first and second tube sections that move telescopically may be selected to provide the appropriate level of friction to achieve a balance between the quality of the seal and the ease of adjusting the first and second tube sections. In some forms of the technology, for example the patient interface **3000** shown in FIG. **7**B, it has been found that a minimum retaining force between the first and second tube sections **3370**, **3372** may be approximately 10N and a maximum retaining force may be approximately 20N. If the retaining force is less than the predetermined minimum amount the first and second tube sections may move apart too easily and the length of tubes **3350** may be accidentally adjusted during normal use of the patient interface **3000**, for example by being jogged by the patient or the patient's bedding, or as a result of the flow of gas at positive pressure through the tubes **3350**. If the retaining force is more than the predetermined maximum amount the first and second tube sections may be too difficult for a patient to move to adjust the length of the tubes **3350**.

In an alternative form of the technology, the inner or outer surface of the first or second tube portions **3370**, **3372** may comprise one or more moveable flap seals, lip seals or a compressible gasket seal. In another form, there may be a controlled leak between the first and second tube portions **3370** and **3372**, such that the leak does not interfere with respiratory pressure therapy. In one form, the controlled leak may act as an additional washout vent.

In the above-described forms of the technology in which one or more tube sections are telescopically movable relative to other tube sections, the patient interface **3000** may comprise one or more end stops to prevent the first tube section **3370** and the second tube section **3372** from coming apart. In one form, the inner tube section comprises a flange at its end, and the outer tube section comprises an end stop on an inner surface against which the flange abuts at the maximum extension of the tube sections.

Although a swivel elbow has been described, it is possible a ball and socket elbow may be used instead to provide six degrees of freedom for providing greater decoupling of tube drag forces.

8.3.3.3.3 Modular Tube Portions

FIG. **11** shows a patient interface **3000** in which the adjustment mechanism **3360** takes the form of a replaceable tube portion **3385** which can be removed from the patient interface **3000** and replaced with a replacement tube portion **3386** having a different length to the first tube portion or module **3385**. The replaceable and replacement tube portions **3385** and **3386** may be described as tube modules.

In the example of FIG. **11**, the replaceable tube portion **3385** comprises a T-shaped tube member that has three ports so that the replaceable tube portion **3385**, in use, fluidly connects to each of tubes **3350** and the air circuit **4170**. For example, a central port in the upper side of replaceable tube portion **3385** is configured to connect to connection port **3600** or comprise connection port **3600**. For example, replaceable tube portion **3385** may be positioned in use on top of the patient's head.

Tube portion **3385** is able to be disconnected from the other parts of patient interface **3000** and replaced with replacement tube portions **3386***a* and **3386***b*. Replacement tube portions **3386***a* and **3386***b* have tube sections extending outwards from connection port **3600** by a differing amount to replaceable tube portion **3385**. Any number of replacement tube portions may be provided but in the embodiment of FIG. **11**, patient interface **3000** comprises 'small', 'medium' and 'large' replaceable portions.

In the form of the present technology shown in FIG. **12**, patient interface **3000** comprises one or more tube insert members **3387***a* and **3387***b* configured to be selectively fluidly connected to the tub **3350** to alter the length of the tube. For example, tube insert members **3387***a* and **3387***b* are configured to be fluidly connected between tubes **3350** and cushion assembly **3150** to alter the effective length of tubes **3350**. In alternative embodiments, the tube insert members may be connected to other parts of the patient interface, for example at an upper end of the tubes **3350** between the tubes **3350** and the connection port **3600**. Each tube insert member **3387** may be marked with a size indication, for example 'M' for medium and 'L' for large and the like. One size of patient interface may be achieved with no tube insert members connected.

8.3.3.3.4 Cuttable Tubes

In another embodiment of the present technology, the tubes **3350** may be cut to the desired length. To assist the patient or clinician to determine where to cut the tubes **3350**, the tubes may comprise one or more indicators indicating where to cut the tube for fitting the patient interface to different sizes heads. For example, lines or perforations may be provided around the diameter of the tubes **3350** to indicate where they may be cut. Each line or perforation may be marked with a size marking, for example 'small', 'medium' or 'large'. The cut markings on tubes **3350** may be provided on the lower ends of the tubes configured to connect to the cushion assembly **3150** or on the upper ends of the tubes configured to connect to the connection port **3600**.

In one embodiment, a patient interface is supplied with a cutting tool configured to cut tubes **3350**.

One disadvantage of cutting tubes **3350** to tailor the size of the patient interface is that, if the tubes are mistakenly cut too short, the cut off sections of tube may be difficult to replace.

8.3.3.3.5 Stretchable Tubes

In certain forms of the present technology the adjustment mechanism comprises one or more stretchable sections **3355** of headgear tubes **3350** formed of a stretchable material. Stretchable sections allow the length of tubes **3350** to be adjusted continuously to fit different sizes of patient heads. It will be appreciated that a section of tube may be stretchable by virtue of the material it is made from (e.g. if it is made from stretchable material), its configuration (e.g. the concertina tube section **3362** shown in FIG. **3**A is stretchable by virtue of its configuration), or both.

FIG. **13** illustrates a headgear tube **3350** having a relatively stretchable section of tube **3355** connected to one or more non- or less stretchable sections of tube **3354**. A securing mechanism **3356** may be provided to hold the tube **3350** in position when the desired length is attained. Securing mechanism **3356** may comprise a first securing member **3357** mounted on a length of tube **3350** on one side of the stretchable section **3355** and a second securing member **3358** mounted to a length of tube **3350** on the other side of the stretchable section **3355**. First and second securing members **3357** and **3358** are configured to connect together by any appropriate mechanism, for example an interlocking clip, magnet connection, hook-and-loop fasteners. One of the securing members **3358** may comprise a plurality of sites at which the other securing member **3357** may connect to it to allow the tube **3350** to be secured at the desired length.

In another embodiment no securing mechanism is provided and the length of the tube **3350** is achieved automatically by the elastic contraction of the stretchable section **3355**.

The stretchable section of tube **3355** may comprise a section that is thinner than the less stretchable sections **3354**. Alternatively or additionally the stretchable section of tube **3355** may comprise a section that is formed from a material that is softer and/or has a lower durometer rating than the less stretchable sections **3354**.

In one embodiment a stretchable section of tube **3355** has a cross-sectional thickness that reduces along its length. For example, the cross-sectional thickness may reduce in stepped longitudinal sections. Alternatively, the cross-sectional thickness of the tube section **3355** may alternate between thicker and thinner longitudinal sections. The surface transition between sections of differing cross-sectional thickness may be smooth or abrupt. The regions of differing cross-sectional thickness may have different rigidities and/or durometer ratings. The regions of differing cross-sectional thickness may be formed from the same or different materials. By selecting the structure of the stretchable section of tube **3355** using different materials and different cross-section thicknesses, specific sections of tube **3350** may be designed to stretch more than others. This may help the patient interface to fit differing patients by enabling parts of the tube **3350** that, in use, are positioned over parts of patients' anatomy that have particularly differing sizes between individuals to be made to stretch more than other parts. In addition, or alternatively, the stretchable section of tube **3355** may be designed to, in use, substantially maintain a pre-determined minimum aperture area so that the impedance of the patient interface to the flow of breathable gas can be configured to suit the respiratory treatment system, for example the desired rate of flow of gas.

8.3.3.3.6 Different Tube Connection Positions

In certain forms of the present technology, the tubes **3350** are able to be connected in a plurality of ways which enables the effective length of the fluid path between the connection port **3600** and the seal-forming structure **3100** to be adjusted.

In certain forms, each tube **3350** comprises two or more separate tube members able to be fluidly connected together at multiple positions to alter the length of the fluid path formed by the tube members. In one form, a first tube member comprises a plurality of ports along a side and a second tube member comprises one or more tubes protruding from a side of the second tube member and able to mate with selected ports in the first tube member to fluidly connect the first and second tube members. The length of the tube **3350** formed by the first and second tube members may be adjusted by selection of which ports the protruding tubes on the second tube member is connected to. The ends of the first and second tubes members adjacent to the connecting ports and protruding tubes are sealed so breathable gas passes only through each tube member and does not intentionally leak. Also the ports on the side of the first tube member may be provided with automatically closing valves to avoid leakage of gas if those ports are not connected to the second tube member.

In some forms of the technology, multiple tube connections are provided at the connection port and/or at the cushion assembly **3150**. For example, the plenum chamber **3200** may comprise two or more ports on each side to which the tubes **3350** may selectively be fluidly connected. The ports may be arranged such that adjustment of which port the tubes are connected to alters the size of patient the patient interface fits. For example one port may be positioned so that, in use, it is closer to the patient's face than another port. Connection of the tube **3350** to a port closer the patient's face will accommodate a larger patient head than connection of the tube **3350** to a port further from the patient's face.

8.3.3.3.7 Alteration of Patient Interface Loop

Certain forms of the present technology comprise a patient interface **3000** in which the positioning and stabilising structure **3300** defines a loop configured to, in use, encircle a part of the patient's head. For example one or more ties may define a loop that encircles part of the patient's head in some forms of the technology. For example, in the embodiment shown in FIG. **3**A, the loop is defined by the tubes **3350** and the cushion assembly **3150**. These components create a loop within which the patient's head is positioned when the patient interface **3000** is being worn.

In some forms of the present technology the positioning and stabilising structure between the connection port **3600** and the seal-forming structure **3100** of cushion assembly **3150** is adjusted by an adjustment in the size of this loop. Adjustment of this loop enables the patient interface to be tailored to fit different sized patients. Previously described embodiments show how the size of the loop may be adjusted by alteration of the length of the tubes **3350**. There will now be described embodiments in which other mechanisms for adjusting the size of the loop are provided.

8.3.3.3.8 Loop Adjustment Mechanisms

In certain forms of the present technology, the patient interface **3000** comprises a loop adjustment mechanism that is operable to adjust the position at which two regions of the positioning and stabilising structure **3300** are held together to adjust the size of the loop.

In FIG. **5**, the patient interface **3000** comprises a strap **3390** connected between the tubes **3350**. The strap **3390** is positioned towards an upper end of the patient interface **3000** below connection port **3600** such that, in use, it passes over the top of the patient's head, or proximate thereto. The strap **3390** may be upwardly curving to accommodate the top of the patient's head. The strap **3390** may be formed of a flexible, rigid or semi-rigid material.

In this embodiment, a loop of the patient interface **3000** that encircles a part of the patient's head when the patient interface **3000** is worn is defined by the strap **3390**, the cushion assembly **3150** and the parts of tubes **3350** connected between strap **3390** and cushion assembly **3150**. The size of this loop may be adjusted by adjusting the strap. The patient interface comprises a strap adjustment mechanism **3391** by which the length of the strap **3390** may be adjusted. Strap adjustment mechanism **3391** may comprise an adjustable fastening attachment between two sections of the strap **3390**. For example, one section of the strap **3390** may pass through a loop attached to the end of the other section of the strap **3390** and attach to itself using a hook-and-loop material. Alternatively, the two strap sections may be able to be connected together using poppers or interlocking members that can connect in a plurality of different positions. In another embodiment, two sections of strap **3390** each comprise rack portions which engage with a pinion or cog and the length of the strap **3390** can be adjusted by rotation of the cog. In another embodiment, the two sections of the strap **3390** are telescopically slideable relative to each other and may be secured in place via an interlocking mechanism, magnets or frictional engagement.

In further alternative embodiments, one or both ends of the strap **3390** may connect to the tubes **3350** by an adjustable strap connection mechanism such that the position at which the strap **3390** connects to one or both tubes **3350** can be varied.

Another form of the technology is shown in FIG. **14**. In this form, patient interface **3000** comprises a band **3395** positioned around the upper ends of the tubes **3350**, i.e. the ends of the tubes closest to the connection port **3600**. Band **3395** holds the tubes **3350** together at their upper end and its position determines the size of the loop defined in part by the tubes **3350** which encircles a part of the patient's head when the patient interface **3000** is worn. During use the band **3395** may be moved along the tubes **3395** to alter where the tubes **3350** are held together and thus alter the size of the loop defined by the patient interface **3000**. Moving band **3395** along the tubes **3350** towards the connection port **3600** makes the size of the loop larger so the patient interface can fit a larger head.

Band **3395** may be secured tightly around tubes **3350** with a high level of friction between the band and the tubes so that it cannot easily slide upwards and loosen during use. For example, the band **3395** may be formed from rubber or other high friction material. Alternatively, the patient interface may comprise a mechanism to secure the band in position. For example, a plurality of ridges and/or protrusions may be provided on the outer edges of tubes **3350** and one or more detents may be provided on the inner surface of band **3395** to interlock with the ridges/protrusions of the tubes **3350** and secure the band in position. The detents may be disengaged from the ridges/protrusions by an appropriate mechanism to enable the band to be moved along the tubes **3350** when desired.

In another embodiment upper sections of the two tubes **3350** are secured together by a clasp locker or zip. For example, one row of teeth of the clasp locker may be mounted on one tube **3350** and another row of teeth of the clasp locker may be mounted on the other tube **3350**. The slider is moveable between the rows of teeth to adjust the position at which the two tubes **3350** are held together to alter the size of the loop formed by the patient interface **3000** are thereby accommodate different patient head sizes.

8.3.3.3.9 Loop Inserts

In certain forms of the present technology, the positioning and stabilising structure **3300** comprises one or more loop insert members configured to be secured to another part of the patient interface **3000**, for example directly or indirectly secured to the tubes **3350**. The loop insert member(s) is configured to be secured so that it defines, at least in part, the loop which, in use, encircles part of the patient's head. By adjusting the size of the loop insert member, or by replacing the loop insert member with a loop insert member of a differing size, the size of the loop can be adjusted to accommodate different sizes of patient heads.

One form of the present technology is shown in FIG. **15**. In this form, patient interface **3000** comprises a loop insert member **3410** that is connected to the underside of tubes **3350** and connection port **3600** and, in use, is positioned between the patient's head and the tubes **3350** and connection port **3600**. Loop insert member **3410** acts to change the size of the loop that encircles a part of the patient's head compared to the size of the loop formed by the tubes **3350** if the loop insert member is not present.

Loop insert member **3410** is removably attached to tubes **3350**. Loop insert member **3410** may therefore be removed and replaced by one or more replacement loop insert members **3411***a*, **3411***b* or **3411***c*. Replacement loop insert members **3411***a*, **3411***b* or **3411***c* differ in size from loop insert member **3410** and by selection of the loop insert members the size of the loop for encircling a part of the patient's head can be adjusted and consequently the patient interface can be adapted to fit the patient more comfortably and more securely. The ability to remove the loop insert members **3410** and **3411** is also beneficial so that they can be cleaned.

Loop insert members may be formed from a rigid or semi-rigid material able to space the tubes **3350** from the patient's head in use and thereby alter the shape of the loop encircling the patient's head. A material that has some resilience and give may provide more comfort when worn, for example a foam or gel material. Since the loop insert members are in contact with the patient's hair or skin when worn they are preferably made from a material that is easily cleaned.

The loop insert members **3410** and **3411** shown in FIG. **15** are generally U-shaped with the apex of the 'U' positioned in use at the top of the patient's head below the connection port **3600**. This helps the patient interface to conform to the shape of the top of the patient's head. In other embodiments, different shaped insert members are used, for example an insert member may comprise a short straight pad configured to contact a small part of the patient's head. Different sized replacement insert members **3411** may have different thicknesses, different lengths, and/or different degrees of curvature. The patient contacting surface of each insert member may be the same or similar to conform to the patient's head shape irrespective of which insert member is used.

The loop insert members **3410** and **3411** are attached to the tubes **3350** by a fastening mechanism. In one embodiment the fastening mechanism comprises hook-and-loop material attached to the underside of tubes **3350** and the upper side of loop insert members **3410** and **3411**. In other embodiments, poppers, domes, clasp lockers or magnets are used to connect loop insert members **3410** and **3411** to the tubes **3350**.

In the embodiment of FIG. **15** the patient interface **3000** comprises a single loop insert member **3410** and the replacement loop insert members **3411** are single or monolithic components. In other embodiments, multiple loop insert members are able to be attached to the tubes **3350** at any one time. For example, multiple loop insert members may be able to be attached along the length of tubes **3350** to act as a plurality of spacers spacing different parts of the patient's head from the tubes **3350**. In another embodiment, multiple of the loop insert members **3410** and the replacement loop insert members **3411** may be mounted on the tubes **3350** at any one time. For example, different sized loop insert members may be able to be nested. To achieve this, the loop insert members **3410** and **3411** may be able to connect to each other, for example using any of the loop insert member connection mechanisms mentioned above.

In the form of the present technology illustrated in FIG. **16** the patient interface **3000** comprises an inflatable loop insert member **3420**. Inflatable loop insert member **3420** may comprise a bladder provided on an inner surface of tubes **3350**. The bladder has a sealable opening into which air can be introduced or released to alter the size of the bladder and consequently adjust the size of the loop defined by the patient interface **3000** which encircles part of the patient's head in use. In one embodiment, the patient interface comprises a pump button which can be repeatedly depressed to introduce air into the bladder through a valve.

In the form shown in FIG. **16** the patient interface comprises a single U-shaped bladder **3420** that is connected to each tube **3350** on either side of and on top of the patient's head. The thickness of the bladder **3420** may be largest at the top of the patient's head to accommodate a symmetrical movement of the tubes **3350** away from the surface of the patient's head as the bladder is inflated. In other embodiments, multiple inflatable bladders are mounted on the tubes **3350**. These inflatable bladders may be inflatable together or separately. Separately inflatable bladders allows a patient to alter the fit of the patient interface as desired, for example by inflating a bladder on one side of the head more than the other side.

8.3.3.3.10 Magnitude of Dimensional Adjustment of Headgear Tubing

As discussed previously, the positioning and stabilising structure **3300** may be configured to be worn with the upper portion of the headgear tubing **3350** positioned differently for different patients. For example, the position of the connection port **3600** on the patient's head during use may vary within a range of forward/rearward positions in the sagittal plane. The circumference of a patient's head around which the headgear tubing **3350** fits may be smaller if the upper portion of the headgear tubing **3350** is worn further forward compared to if the headgear tubing **3350** was worn further back. In some forms, the positioning and stabilising structure **3300** allows a patient with a large head size to wear the upper portion of the headgear in a more forward (e.g. anterior) position on their head, reducing the magnitude of length adjustment that is needed from the adjustment mechanism **3360** to accommodate the large head size.

FIG. **3**J shows three depictions of a patient interface **3000***a, b, c* according to one form of the technology, each depiction of the patient interface **3000** being shown in a different position on the patient's head, for comparison. The patient interface **3000***b* is shown in solid lines in a central position, while the patient interfaces **3000***a* and **3000***c* are shown in phantom and are worn forwardly and rearwardly, respectively. In each of the depictions in FIG. **3**J, the adjustment mechanism **3360** has substantially the same length. That is, the adjustment mechanism **3360** is not extended or contracted between the depictions labelled "a", "b" and "c". While there is no change in length of the adjustment mechanism **3360**, the patient interface **3000***a* (the forward position) can fit over a larger head (shown in phantom) since it is worn forward. Similarly, the patient interface **3000***c* (rearward position) can fit properly to a smaller head (shown in phantom) with the same length of adjustment mechanism **3360**.

In one depiction in FIG. **3**J, identified by reference numerals labelled "b", the patient is wearing the headgear in a central position, in which the adjustment mechanism **3360***b* and connection port **3600***b* are approximately aligned vertically. The connection port **3600***b* is located centrally in the anterior-posterior axis. That is, the connection port **3600***b* is located in a central position rather than in a generally forward (e.g. anterior) position or a generally backward (e.g. posterior) position. The connection port **3600***b* is located approximately at a top point of the patient's head. The connection port **3600***b* may be positioned in the sagittal plane and aligned with the otobasion superior points in a plane parallel to the coronal plane. The otobasion superior points are identified in FIG. **2**D.

In another depiction in FIG. **3**J, identified by reference numerals labelled "a", the patient is wearing the headgear tubing **3350***a* in a relatively forward (e.g. anterior) position compared to the position of headgear tubing **3350***b*. In this configuration, the connection port **3600***a* is positioned generally forward of the adjustment mechanism **3360***a*. In this position, the connection port **3600***a* is anterior to the otobasion superior points. In another depiction in FIG. J, identified by reference numerals labelled "c", the patient is wearing the headgear tubing **3350***c* in a relatively rearward (e.g. posterior) position compared to the position of headgear tubing **3350***b*. In this configuration, the connection port **3600***c* is positioned generally rearward of adjustment mechanism **3360***c*. In this position, the connection port **3600***c* is posterior to the otobasion superior points.

When worn in the position depicted by headgear **3300***a* in FIG. **3**J, the headgear tubing **3350***a* will generally fit around a smaller circumference of the patient's head, enabling the positioning and stabilising structure **3300** to be worn in a relatively forward position to accommodate a patient with a larger head (shown in phantom). Similarly, when worn in the position depicted by positioning and stabilising structure **3300***c* in FIG. **3**J, the headgear tubing **3350***c* will generally fit around a larger circumference of the patient's head, enabling the positioning and stabilising structure **3300** to be worn in a relatively rearward position to accommodate a patient with a smaller head (shown in phantom). The positioning and stabilising structure **3300** may be worn in a continuous range of positions between a generally forward position and generally rearward position depending on the patient's head size, head shape, personal preference, among other factors. In some forms the present technology the positioning and stabilising structure **3300** is configured to be

worn such that the connection port **3600** is positioned in use up to approximately 20 mm forward (e.g. anterior) of a central position at a top point of the head, and up to approximately 20 mm rearward (e.g. posterior) of the central position. In some forms of the technology the upper portion (e.g. the portion above the rear strap **3310**) of the headgear tubes **3350** are configured to flex, bend and move in forward or rearward directions substantially without corresponding movement in the lower portion or non-adjustable tube section **3363** (e.g. the portion below the rear strap **3310**). In other forms of the technology, the upper portion and lower portion may move together (although not necessarily to the same extent). The rear strap **3310** may be configured to prevent or resist movement of the non-adjustable tube section **3363**. For example, by moving the upper portion of the headgear tubes **3350** forward on a patient's head without loosening the rear strap **3310**, more movement of the upper portion of the headgear tubes **3350** may be required in comparison to the non-adjustable tube portion **3363**.

Separately to the ability of the positioning and stabilising structure **3300** to be worn in different forward/rearward positions, in some forms of the technology the headgear tubing adjustment mechanism **3360** enables the positioning and stabilising structure **3300** to fit to different sized heads. The headgear tubing adjustment mechanism **3360** may be configured to provide a predetermined amount of length adjustment to the headgear tubing **3350**. An amount of adjustment to the length of the headgear tubing **3350** may be determined based at least partly on a range of head sizes for which the positioning and stabilising structure **3300** is configured to accommodate. In some forms of the present technology the adjustment mechanism **3360** may be enable the headgear tubes **3350** to increase in length by an amount between approximately 10 mm and 50 mm, inclusive, on either side of the positioning and stabilising structure **3300**. In some forms of the present technology the increase in length may be an amount between 20 mm and 40 mm, inclusive, on either side. In some forms of the present technology the increase in length provided may be any one of substantially 25 mm, 30 mm, 35 mm, or 40 mm on either side.

FIG. **3**K shows a patient interface **3000** with positioning and stabilising structure **3300** having headgear tubes **3350** and a headgear tube adjustment mechanism in a first configuration identified with the reference numeral **3360**. The adjustment mechanism **3360** is also shown in phantom in a second configuration and identified with the reference numeral **3360'**. In the first configuration of the adjustment mechanism **3360** the headgear **3300** fits around a patient with one size head and in the second configuration of the adjustment mechanism **3360'** the headgear **3300** fits around a patient with a larger head. In this form of the technology, the adjustment mechanism **3360'** enables an extension of the length of the headgear tubes **3350** in order to fit around the larger head. As shown in FIG. **3**K, the adjustment mechanism **3360/3360'** enables the headgear to adjust (or be adjusted) to accommodate different head sizes while worn in a central position (e.g. with the connection port **3600/3600'** positioned centrally at a top point on the head rather than forward or backwards).

In some forms of the present technology the adjustment mechanism **3360** is also able to enable length adjustment of the headgear tubes **3350** when the headgear **3300** is worn in forward, central and/or rearward positions. FIG. **3**L shows a patient interface **3000** with headgear **3300** worn in three positions on a patient's head, as identified by reference numerals suffixed with "a", "b" and "c". The positioning and stabilising structure **3300***a* is worn in a forward position, positioning and stabilising structure **3300***b* is worn in a central position and positioning and stabilising structure **3300***c* is worn in a rearward position. That is, the connection port **3600***a* is in a forward position on the patient's head, while the connection port **3600***b* is in a central position and connection port **3600***c* is in a rearward position. In the forward position, the headgear tubes **3350***a* fit around a smaller circumference of the patient's head in comparison to the circumference that the headgear tubes **3350***b* fit around in the central position. To accommodate this smaller circumference the adjustment mechanism **3360***a* in the forward position provides a reduction in the length of the headgear tubes **3350** (or less of an extension). In the rearward position the circumference of the patient's head around which the headgear tubes **3350***c* fit is larger than the circumference in the central position. To accommodate this larger circumference, the adjustment mechanism **3360***c* provides an increase in length of the headgear tubes **3350** in comparison to their length in the central position.

The combination of the different positions in which the positioning and stabilising structure **3300** can be worn, and the different amounts of length adjustment provided by the adjustment mechanism **3360**, provides versatility in the adjustment options available to patients. This versatility may result in a wide range of head shapes and sizes being accommodated by the positioning and stabilising structure **3300** without excessive discomfort and while enabling a sufficient seal of the seal forming structure **3150** to the patient's face. In some embodiments, the adjustment mechanism **3360** provides for a lower magnitude of length adjustment, as patients with larger head sizes are able to wear the upper portion of the headgear tubing **3350** in a forward position, rather than relying solely on the adjustment mechanism **3360** to accommodate their large head size. In other embodiments the adjustment mechanism **3360** provides for a large magnitude of length adjustment, and the ability for patients with larger head sizes to wear the upper portion of the headgear tubing **3350** further forward means that the patient interface **3000** may be suitable for a large range of head sizes.

8.3.3.4 Position of Headgear Tubing Adjustment Mechanism

It is generally desirable to avoid features of patient interfaces causing a patient discomfort. Therefore patient interfaces may be designed with few components contacting the patient's skin and those that do contact the patient's skin may be soft and/or smooth. The cheek region is known to be a source of patient discomfort when wearing patient interfaces.

Mechanisms allowing the positioning and stabilising structure to be adjusted, such as those described above, may comprise features that cause discomfort to a patient if contacting a patient's face or head, particularly the cheek region. Therefore certain forms of the present technology comprise positioning and stabilising structures configured such that, when the patient interface is worn, the adjustment mechanism or parts thereof are positioned out of contact with areas of the patient's skin or hair, for example out of contact with the patient's face or out of contact with the patient's cheek regions. In some forms of the technology the adjustment mechanism is positioned higher than a patient's ears, i.e. superior to the otobasion superior of the patient's head or proximate a top portion of the patient's head. In these forms of the technology, the headgear tubes comprise a non-adjustable headgear tube section that is positioned adjacent to the patient's face in use, i.e. in a position where the non-adjustable headgear tube section might come into contact with the patient's face during use of the patient interface. For example, in some forms, the non-adjustable headgear tube section is positioned adjacent to the patient's cheek regions when worn and only non-adjustable headgear tube sections are adjacent to the patient's cheek regions, inferior to the otobasion superior of the patient's head or overlaying a maxilla region of the patient's head in some forms of the technology.

It will be understood that a non-adjustable headgear tube section is a section that is not specifically configured to be dimensionally adjusted during use, i.e. the adjustment mechanism does not form part of the non-adjustable headgear tube section. This does not preclude, however, the non-adjustable headgear tube section being able to be dimensionally adjusted if, for example, excessive force is imparted on it. The position of the non-adjustable headgear tube section may, however, be adjusted during use. In some forms of the present technology, non-adjustable headgear tube sections may be substantially non-adjustable in axial length, but may be adjustable in other ways such as by flexing, curving, straightening, and the like. For example, as shown in FIG. **3**L, the non-adjustable headgear tube sections **3363***a, b* and *c* are configured to bend or curve to different extents in order to facilitate the different positions in which the positioning and stabilising structure **3300** is worn on the head, with different amounts of extension provided by the adjustment mechanism **3360***a, b* and *c*.

Locating the adjustment mechanism out of the patient's field of view may also be beneficial to avoid a feeling of claustrophobia or an interrupted view.

In the case of the form of patient interface **3000** shown in FIGS. **3**A, **3**B, **3**C, **3**D, **3**E and **3**F, for example, the concertina sections **3362** are positioned on either side of the patient's head between the ears or ear level and the crown or top of the head and non-adjustable headgear tube sections **3363**, which form the lower ends of the headgear tubes (i.e. the inferior ends when worn by a patient) are positioned adjacent to (or over) the patient's cheek region when worn. Other examples of non-adjustable headgear tube sections **3363** are shown in FIGS. **5**, **7**A, **7**B, **7**C and **17**.

In certain forms of the present technology the non-adjustable headgear tube sections **3363** are configured such that they assist in maintaining an adequate seal between the cushion assembly **3150** and the patient's face during use of the patient interface **3000**. This may require the flexibility (or stiffness) of the non-adjustable headgear tube sections **3363** to be selected so that they are sufficiently stiff so as not to deform too easily during use while being sufficiently flexible to accommodate some movement during use and some variation in the position in which individual patients wear the patient interface **3000**.

Rear headgear strap **3310** stabilises the headgear tubes **3350** on the patient's head but the lower ends of the headgear tubes **3350** are more freely able to move, particularly at points relatively far from the point at which rear headgear strap **3310** connects to the headgear tube **3350**. An overly flexible lower end of a headgear tube **3350** tends to allow the cushion assembly **3150** to roll forward away from the patient's face, which disrupts the seal. This rolling forward effect can be mitigated by increasing the stiffness of the lower end of the headgear tubes **3350**, i.e. the non-adjustable headgear tube section **3363** in the forms of the technology shown in FIGS. **3**A, **3**B, **3**C, **3**D, **3**E, **3**F, **5**, **7**A, **7**B, **7**C and **17**. For the purposes of this discussion, the lower end of the headgear tubes **3350** may be considered to be the part of the headgear tubes **3350** positioned below (i.e. inferior to, when the patient interface **300** is worn by a patient) the point at which rear headgear strap **3310** connects to each headgear tube **3350** as this point is stabilised on the patient's head and therefore may tend to act as a pivot point to any movement of the headgear tubes **3350** below that point. It will be understood that other arrangements of headgear straps may lead to a different positioning of an effective pivot point.

For a similar reason it may be advantageous for the lower end of the headgear tubes **3350** to be free of any adjustment mechanisms in some forms of the technology. Locating a concertina section, for example, on the headgear tubes **3350** at a point below where the rear headgear strap **3310** connects to the headgear tubes **3350** means that the concertina section tends to buckle and distort if movement occurs and acts as a natural pivot, allowing movement of the cushion assembly, which could disrupt the seal with the patient's face.

Furthermore, an adjustment mechanism **3360** on the upper portion of headgear tube **3350** (which is considered, for the purposes of this discussion, to be the part of the headgear tubes **3350** positioned above, i.e. superior to, the point at which the rear headgear strap **3310** connects to each headgear tube **3350**) helps to de-couple the upper and lower portions of the headgear tube **3350** so that movement of the upper portion (either during use or by virtue of variations in positioning of the patient interface **3000** on the patient's head) do not exert excessive forces on the cushion assembly **3150** that may tend to disrupt the seal with the patient's face. In particular, an adjustment mechanism **3360** in which the length of the headgear tube **3350** can be extended helps avoid straightening of non-adjustable headgear tube sections **3363** in the lower end of headgear tube **3350** as this kind of adjustment mechanism **3360** enables the lower end of the patient interface **3000** to move up and down relative to the patient's head (i.e. in the inferior and superior directions). Excessive straightening and/or stretching of the non-adjustable headgear tube sections **3363** may also cause the cushion assembly **3150** to roll forward, disrupting the seal to the patient's face.

In some forms of the technology, the radius of curvature of a non-adjustable headgear tube section **3363** (or lower end of the headgear tube **3350**) also affects the degree of movement of the upper end of the headgear tubes **3350**. The larger the radius of curvature the greater the de-coupling effect between the upper and lower ends of the headgear tubes **3350** so that the upper end of the headgear tubes **3350** can move without causing significant rolling forward to the cushion assembly **3150** and consequent loss of seal.

In some forms of the present technology, the provision of the adjustment mechanism **3360** on the upper portion of the headgear tube **3350**, proximate the connection port **3600** may help to alleviate tube drag on the head as it allows the connection to decouple through stretch and flex provided by the adjustment mechanism.

In some forms of the present technology, providing the adjustment mechanisms **3360** on the upper portions of the headgear tubes **3350**, spaced far from the cushion assembly **3150**, may reduce effects on the cushion assembly **3150** caused by differences in the extension of the headgear tubes **3350**. For example, effects of imbalances in the extension of, and/or any forces exerted by, the adjustment mechanism **3360** on either side of the patient's head may be less pronounced. Such effects may compromise the seal formed by the cushion assembly **3150** to the patient's face.

In other forms of the present technology the adjustment mechanism may be positioned close to the cushion assembly **3150** of the patient interface and be spaced from the patient's face by virtue of the size of the plenum chamber and the location of the port to which the tube **3350** connects to the plenum chamber distancing the lower end of the tube **3350** (and consequently the adjustment mechanism) from the patient's skin. The form of the present technology shown in FIG. **10**B is one such example of a patient interface **3000** where the adjustment mechanism is spaced from the patient's face in use.

8.3.3.5 Headgear Tubing Bias Mechanism

In certain forms of the present technology, the positioning and stabilising structure **3300** comprises a bias mechanism which acts in use to urge the seal-forming structure **3100** towards the patient's face, i.e. towards the area surrounding the entrance to the patient's airways to which the seal-forming structure **3100** seals. The bias mechanism therefore acts to help the seal-forming structure **3100** provide a good seal with the patient's face during the use of the patient interface **3000** and to promote the retention of the seal when the patient interface supplies gas under positive pressure to the patient. In some forms of the technology, the bias mechanism acts (i.e. imparts a biasing force) on the adjustment mechanism **3360**. When the plenum chamber **3200** is pressurised the tendency is for the cushion assembly **3150** of the patient interface **3000** to move away from the patient's face. A bias mechanism acting to bias or urge the cushion assembly **3150** towards the patient's face counters this tendency in order to maintain a seal.

In some forms of the technology, the bias mechanism acts to impart a biasing force along at least a part of a length of the headgear tube **3350** to urge the seal-forming structure towards the entrance of the patient's airways in use. In such forms the headgear tube **3350**, or parts thereof, are in tension when in use. In some forms the bias mechanism is comprised as part of the headgear tubing **3350** while in other forms the bias mechanism is distinct from the headgear tubing **3350**.

A bias mechanism may also assist in automatically adjusting the patient interface to fit a particular patient's head.

8.3.3.5.1 Magnitude of Force Exerted by Bias Mechanism

The bias mechanism is preferably configured to apply sufficient inwards (i.e. towards the patient's airway openings) force to maintain a good seal during use while avoiding applying an excessive force. An excessive force may cause the seal-forming structure **3100** to compress and its geometry change so that some parts of the structure move away from the patient's face and gas leaks out of the seal-forming structure. Furthermore, avoiding excessive forces on the patient's face from the patient interface promote comfort and avoid red marks, abrasion or sweating on the patient's face.

In some forms of the present technology, an acceptable force provided by the bias mechanism may be in the region of 0.5-4N on each side of the positioning and stabilising structure **3300**. In some forms an acceptable force may be in the region of 1-3.5N. Forces around 2N may be considered acceptable. In some forms of the present technology the positioning and stabilising structure **3300** is configured to support a seal-forming structure **3100** in the form of a full face or oro-nasal cushion assembly (e.g. such as the seal-forming structures **3100** shown in FIGS. **4**A-**4**E). In some forms of the technology a full face or oro-nasal seal-forming structure **3100** is heavier than other forms of seal-forming structure (e.g. nasal cradle or nasal pillows) due to its larger size and the positioning and stabilising structure **3300** is configured to provide a larger biasing force accordingly to take up the weight or counteract the drag of the heavier seal-forming structure **3100** while still urging the cushion assembly **3150** into the patient's face with a sufficiently large force to maintain an effective seal, without causing excessive discomfort. Additionally, a full face or oro-nasal seal-forming structure **3100** may be subject to a downward (e.g. inferior) force when the patient relaxes or moves their lower jaw (which may be known as "jaw drop"). The positioning and stabilising structure **3100** may also be configured to account for the effects of jaw drop by counteracting the downwards forces received during jaw drop.

In some forms of the present technology, the positioning and stabilising structure **3300** is configured to interchangeably receive seal-forming structures of different sizes, including relatively small or light seal-forming structures such as a nasal cradle cushion assembly and relatively large or heavy seal-forming structures such as an oro-nasal cushion assembly. The positioning and stabilising structure may comprise a bias mechanism configured to support both types of seal-forming structure, by imparting a biasing force sufficiently strong for either type of seal-forming structure, but not excessive so as to cause discomfort.

In some forms of the technology, the positioning and stabilising structure **3300** is configured to provide a sufficient range of force magnitudes in a plurality of adjustment configurations to maintain an effective seal of either a nasal cradle or a full face mask, without being excessively large so as to cause discomfort.

In some forms of the present technology, the bias mechanism is configured to impart a force on the headgear tubes **3350** or portions thereof that urges the headgear tubing to fit around a patient's head. The bias mechanism may be configured to provide forces with magnitudes within a predetermined range. Such a predetermined range may be limited to magnitudes in which the headgear **3300** is both comfortable and able to maintain a sufficient seal of the seal-forming structure **3100** to the patient's face. The bias mechanism may be configured to urge the seal-forming structure **3100** into sealing contact with the patient's face with a force that is not less than a minimum force required for a sufficient seal. That is, the force may be equal to or greater than a minimum sealing force. The bias mechanism may be configured to urge the headgear tubing **3350** to fit to the patient's head with a force that is not larger than a maximum force considered comfortable by the patient. That is, the force may be less than or equal to a maximum comfort force.

In some forms of the present technology, each headgear tube **3350** comprises a force-extension characteristic which results from a relationship between the extension of the headgear tube **3350** and a force imparted to the headgear tube **3350** by the bias mechanism. Alternatively, or additionally, the force-extension characteristic may result from a relationship between the force imparted to the headgear tube **3350** by the bias mechanism and the extension of the headgear tube **3350**. It will be understood that an "extension" refers to a change in overall length of the headgear tubes and does not imply any particular manner in which the change in overall length of the headgear tubes **3350** occurs or the physical structure of the adjustment mechanism.

In certain forms of the present technology, the bias mechanism may provide a biasing force on the headgear tube **3350** which tends to return the headgear tube **3350** or portions thereof to a predetermined length, such as a length prior to adjustment with the adjustment mechanism. In some forms of the technology the bias mechanism imparts a restoring force on the headgear tube **3350**.

As described above, the adjustment mechanism **3360** of a patient interface **3000** according to some forms of the present technology allows an adjustment in length of a headgear tube **3350**. In some embodiments, such as when there is a relationship between biasing force and the extension of a headgear tube **3350**, a first amount of extension of the headgear tube **3350** (e.g. to a first extended length) results in a force provided by the bias mechanism which is equal to or greater than the minimum sealing force. Additionally, a second amount of extension of the headgear tube **3350** (e.g. to a second extended length) may result in a force provided by the bias mechanism which is less than or equal to the maximum comfort force. Furthermore, amounts of extension between the first and second amounts of extension may result in a force imparted by the biasing mechanism that is between the minimum sealing force and the maximum comfort force.

In some forms of the present technology the headgear tubes **3350** may comprise a force-extension characteristic in which, when the headgear tubes **3350** are adjusted to a first amount of extension (e.g. to the extension at which the bias mechanism provides at least the minimum sealing force), the positioning and stabilising structure **3300** accommodates a predetermined minimum head size. Similarly, when the headgear tubes **3350** are adjusted to a second amount of extension (e.g. to the extension at which no more than the maximum comfort force is exerted by the bias mechanism), the positioning and stabilising structure **3300** may accommodate a predetermined maximum head size. At extensions between the first and second amounts of extension the positioning and stabilising structure **3300** may accommodate head sizes between the minimum and maximum predetermined head sizes. The predetermined minimum head size may be, for example, a 5^{th} percentile head size and the predetermined maximum head size may be, for example, a 95^{th} percentile head size of the particular category of person. It will be understood that other measures/ranges may be used to determine minimum and maximum head sizes accommodated by the positioning and stabilising structure **3300**.

FIG. **3I** shows a force-extension plot **6000** illustrating a force-extension characteristic **6300** of a headgear tube **3350** of a patient interface **3000** according to one form of the present technology. The force-extension plot **6000** includes a horizontal extension axis **6100** and a vertical force axis **6200** to illustrate the relationship between the length of the headgear tube **3350** and the resulting force imparted by the bias mechanism.

Three extensions of the headgear tube **3350** are indicated on the extension axis **6100**: zero extension **6105**, a first amount of extension **6110** corresponding to an extension required to accommodate a 5^{th} percentile head size (e.g. a predetermined minimum head size), and a second amount of extension **6120** corresponding to an extension required to accommodate a 95^{th} percentile head size (e.g. a predetermined maximum head size). Two force magnitudes are indicated on the force axis **6200**: a minimum sealing force **6210** and a maximum comfort force **6220**.

In this exemplary form of the technology, the headgear tube **3350** comprises a force-extension characteristic **6300** in which the force imparted by the biasing means is greater than the minimum sealing force **6210** and less than the maximum comfort force **6220** throughout the range of extensions between the first amount of extension **6110** and the second amount of extension **6120**. That is, across the full range of head sizes that are accommodated, a sufficient seal is able to be maintained without discomfort caused by an excessive biasing force.

It will be understood that in some forms of the technology the relationship between extension and biasing force may not be directly proportional. For example, in some forms of the technology there may be a relatively large increase in force during an initial stage of extension, but only minor or no variation in force in the range of extension required to accommodate minimum and maximum predetermined head sizes. The results of an effective seal without discomfort may be achieved if the magnitude of the force remains between the minimum seal force and the maximum comfort force throughout the range of extension between the minimum head size and maximum head size, regardless of the how force varies within the limits.

8.3.3.5.2 Position of Bias Mechanism

In some forms of the present technology, the bias mechanism acts between seal-forming structure **3100** and connection port **3600**. For example, the bias mechanism is comprised of components of the patient interface connected between the seal-forming structure **3100** and connection port **3600** and may urge the seal-forming structure **3100** generally in the direction of the connection port **3600** and/or longitudinally along the length of tubes **3350**.

8.3.3.5.3 Form of Bias Mechanism

The bias mechanism may take a number of forms. In some forms of the technology, the bias mechanism is a separate mechanism to the adjustment mechanism that enables adjustment of the positioning and stabilising structure such as those described above. In such forms the adjustment mechanism enables the patient interface to be adjusted to fit a patient's head while the bias mechanism acts to urge the seal against the patient's face. In other forms, the bias mechanism and adjustment mechanism are provided at least in part by the same features of the patient interface and the adjustment and bias described above are different functions performed by said same features.

In some forms of the technology the bias mechanism comprises an elastic or resilient member or assembly. In some forms the elastic or resilient member or assembly is connected between the seal-forming structure **3100** and the connection port **3600**, for example it is comprised as part of, or is connected to, the tubes **3350** or the connection assembly between the tubes **3350** and the plenum chamber **3200** and/or the connection assembly between the tubes **3350** and the connection port **3600**.

For example, in the form of the technology shown in FIGS. **3**A, **3**B, **3**C, **3**D and **3**E, the bias mechanism comprises the concertina tube portions **3362**. The concertina tube portions **3362** are configured such that they are biased to compressed positions. Consequently the concertina tube portions **3362** act to pull the seal-forming structure **3100** into the patient's face in use.

In some forms of the present technology, there is a relationship between the extension of the concertina tube portions **3362** and a restoring force imparted to the headgear tubes **3350**. The restoring force may be tension in the concertina tube portions **3362**. The concertina tube portions **3362** may have a force-extension characteristic with similarities to the force-extension characteristic discussed in relation to FIG. **3**I.

The concertina tube portions **3362** may be designed to extend to a first amount of extension in which the positioning and stabilising structure **3300** can accommodate a predetermined minimum head size (such as a 5^{th} percentile head size) and also to a second amount of extension in which the positioning and stabilising structure **3300** can accommodate a predetermined maximum head size (such as a 95^{th} percentile head size). The concertina tube portions **3362** may be designed so that, at a first amount of extension, the tension is greater than a minimum force required to create a suitable seal of the seal-forming structure **3100** to the patient's face. At a second amount of extension, the concertina tube portions **3362** may be designed so that the tension does not exceed a maximum force considered comfortable by the patient. In this way, the positioning and stabilising structure **3300** can accommodate a range of head sizes, creating a sufficient seal across the full range without discomfort caused by excessive force.

In certain forms of the present technology, the concertina tube portions **3362** may comprise a concertina profile which provides the concertina tube portions **3362** with a force-extension characteristic such as discussed above. As shown in FIG. **3**G, the concertina tube portions **3362** may comprise walls having a concertina profile having a repeating wave-like pattern with rounded inside troughs and flat outside peaks. The flattened outside peaks provide a smooth flat surface which may comfortably rest against the patient's head. The concertina tube portions **3362** may comprise a plurality of ribs formed in the walls of the headgear tubes **3350** to form the concertina. The ribs may be inwardly extending as shown in FIG. **3**G. Alternatively, or additionally, the concertina tube portions **3362** may comprise a plurality of grooves.

The profile of the concertina tube portions **3362** may be varied to achieve a desired force-extension characteristic. For example, the pitch of the ribs (e.g. peaks/troughs of the concertina waveform) may be reduced to provide a more extendible concertina tube portion **3362** (e.g. generally more extension for a given amount of force). Furthermore, the height of the ribs (e.g. the amplitude of the concertina waveform) may be increased to provide a more extendible concertina tube portion **3362**. Alternatively, a less extendible concertina tube portion **3362** may be produced by increasing the rib pitch, or by reducing the rib height.

Additionally, or alternatively, a longer concertina tube portion **3362** may be provided to increase extendibility. This may be provided by, for example, increasing the number of ribs formed in the wall of the concertina tube portion **3362**.

Additionally, or alternatively, the wall thickness of the concertina tube portion **3362** may be reduced to provide a more extendible concertina tube portion **3362**, or increased to provide a stiffer concertina tube portion **3362**.

Additionally, or alternatively, the material forming the concertina tube portions **3362** may be selected to assist in providing a predetermined force-extension characteristic. In one form of the technology, the material is 50 durometer silicone. Other materials and/or durometer values may also be selected, such as 40 durometer silicone, for example.

Additionally, or alternatively, a different concertina profile shape may be provided to the concertina tube portion **3362**, to achieve a different amount of extension. For example, a concertina tube portion **3362** in which the walls defining the profile are generally more folded together may result in a more extendible concertina tube portion **3362**.

The configuration of the concertina tube portion **3362** may vary along its length. In some forms of the present technology, such as the form shown in FIG. **3**G, the rib height decreases along the length of the concertina tube portion **3362** in the direction away from the connection port **3600** (e.g. the direction towards the non-adjustable headgear tube section **3363**). The rib height may vary between, for example, a range of 0-6 mm, 0-5 mm, 0-4 mm, 1-5 mm and the like. Alternatively the rib height may be constant and may be, for example, 2 mm, 3 mm, 4 mm and the like. The wall thickness may be substantially constant along the length of the concertina tube portion **3362**, or may vary. In some forms of the technology the wall thickness may be between 0.5 mm-1.2 mm, such as 0.6 mm-1 mm, or 0.8 mm and the like. The rib pitch may be between 3.5-5 mm, such as 3.8-4.5 mm, or 4.2 mm and the like.

In other forms of the present technology, the shape and configuration of the concertina tube portion **3362** differs from those parameters mentioned above by way of example.

In the form of the technology shown in FIG. **13** the relatively stretchable section of tube **3355** is resiliently or elastically deformable and has a tendency to return to its non-stretched state. Therefore in use the relatively stretchable section of tube **3355** acts to pull the seal-forming structure **3100** into the patient's face. Alternatively tubes **3350** may be completely formed from a resilient material that tends to return to its non-stretched state when stretched.

Another form of the present technology is shown in FIG. **17**. In this form, patient interface **3000** comprises one or more elastic sleeves **3340** that cover the tubes **3350**. It will be understood that the elastic sleeves **3340** may partly cover the tubes **3350**, for example there may be holes in the sleeves **3340** such as will be described below. Alternatively, the headgear tubes may be considered to comprise both the elastic sleeves and inner gas delivery conduits with the elastic sleeves covering the inner gas delivery conduits. Elastic sleeves **3340** may be formed from any elastic, resilient or stretchable material, for example an elastic fabric such as elastane, that has a tendency to return to its natural size and shape when stretched.

Elastic sleeves **3340** cover tubes **3350** that each comprise a concertina tube section **3362**. The concertina tube section **3362** may or may not be biased to a compressed position. The concertina tube section **3362** allows the length of tubes **3350** to be adjusted so that the patient interface **3000** fits an individual patient while the elastic sleeves **3340** act to pull the seal-forming structure **3100** of cushion assembly **3150** into the patient's face to enhance the seal.

Elastic sleeves **3340** may comprise a single sheet of elastic material or may be formed from multiple sheets of elastic material connected together, for example sewn or glued together. Alternatively, patient interface **3000** may comprise a plurality of separate elastic sleeves, for example one sleeve may cover each of tubes **3350**.

Elastic sleeves **3340** may comprise openings to allow parts of the patient interface to pass through the sleeves. For example, the elastic sleeves may comprise rear or side openings **3342** through which rear headgear straps **3310** connect to tubes **3350**. Additionally or alternatively, the sleeves may comprise a top opening **3343** through which the air circuit **4170** connects to connection port **3600**, or through which connection port **3600** may protrude. The headgear tubes **3350** may contact the patient's head through the openings **3342**.

A concertina tube section **3362** of tube **3350** may be uncomfortable to a patient if it contacts their skin or hair during use. Patients may also find concertina sections unsightly or present the prospect of being uncomfortable to wear even if the concertina does not actually create extra discomfort, either of which may be undesirable. Covering the concertina section **3362** with an elastic sleeve **3340** avoids these problems. An inelastic sleeve may be used in some embodiments to provide the advantage of comfort. The sleeve may be advantageously formed of a soft material that is not uncomfortable if it contacts the patient.

As the elastic sleeve **3340** may be in contact with the patient's hair or skin during use it may easily become dirty from the patient's natural oils. Therefore the elastic sleeve **3340** may be advantageously formed from a material that is easily washed, e.g. fabric. To make it easy for the patient to wash the elastic sleeve **3340** it may be removable from the rest of the patient interface **3000**. For example, the sleeve may comprise a mechanism for securing the sleeve on the tubes **3350** that can be disengaged for the sleeve to be removed. For example the elastic sleeve **3340** may wrap around the tubes **3350** and connect to itself by clips, poppers, hook-and-loop material or other suitable fasteners.

In some forms of the technology the elastic sleeve **3340** is formed from a material or textile that helps wick moisture away from the patient's face. This may help to maintain comfort if the patient sweats while wearing the patient interface.

In other forms of the technology, elastic sleeves may cover tubes or other parts of the positioning and stabilising mechanism having other adjustment mechanisms such as those described above. Sleeves may be beneficial in covering mechanisms or components that appear complicated or medical which may deter the patient from wearing the patient interface.

In other forms of the technology, telescopically adjustable headgear tubes may comprise a bias mechanism acting to contract the telescopically movable headgear tube sections, for example a spring.

An advantage of manually adjustable adjustment mechanisms which may also provide a biasing force, such as the adjustment mechanism **3360** shown in FIG. **7**C, is the ability to support both relatively heavy and relatively light seal-forming structures in a modular design, i.e. where different types of seal-forming structures can be interchanged. For example, if the cushion assembly **3150** of the embodiment shown in FIG. **7**C is replaced with a heavier oro-nasal cushion assembly the patient is able to manually adjust the length of the headgear tubes **3350** to a shorter configuration to counteract the weight of the oro-nasal cushion and prevent the cushion from sagging downwards or being pushed downwards by movement of the patient's lower jaw.

8.3.4 Vent

In one form, the patient interface **3000** includes a vent constructed and arranged to allow for the continuous flow or washout of exhaled gases, e.g. carbon dioxide (CO_2) from an interior of the plenum chamber to ambient to reduce the risk of the patient rebreathing such gases. That is, the vent allows the flow of patient exhaled CO_2 to an exterior of the patient interface. The vent is sized and shaped to maintain the therapeutic pressure in the plenum chamber.

One form of vent in accordance with the present technology comprises a plurality of holes, for example, about 20 to about 80 holes, or about 40 to about 60 holes, or about 45 to about 55 holes.

The vent may be located in the plenum chamber **3200**. Alternatively, the vent may be located in another part of the patient interface, e.g., a tube **3350** fluidly connecting connection port **3600** with the plenum chamber **3200**.

8.3.5 Decoupling Structure(s)

In one form the patient interface **3000** includes at least one decoupling structure, for example, a swivel or a ball and socket. The decoupling structure may be arranged at or proximate the connection port **3600** to permit the conduit of the air circuit **4170** to move relative to patient interface **3000** and reduce the risk of de-stabilising the seal of the seal-forming structure **3100** against the patient's face.

8.3.6 Connection Port

Connection port **3600** allows for connection to the air circuit **4170**. In the embodiments of the technology shown in FIGS. **3** and **5**-**17**, for example, the connection port is positioned on top of the patient's head when the patient interface **3000** is being worn. In other embodiments, the connection port is configured to be positioned, in use, proximal a top, side or rear portion of the patient's head. Patient interfaces in which the connection port is not positioned in front of the patient's face may be advantageous as some patient's find a conduit that connects to a patient interface in front of the face to be unsightly and obtrusive. For example, a conduit connecting to a patient interface front of the face may be prone to being tangled up in bedclothes, particularly, if the conduit extends downwardly from the patient interface in use.

8.3.7 Forehead Support

In one form, the patient interface **3000** includes a forehead support for contacting the patient's forehead region to support the patient interface on the patient's head during use and helping to maintain the sealing structure in sealed contact with the patient's face.

8.3.8 Anti-Asphyxia Valve

In some forms of the technology the patient interface **3000** is constructed and arranged to allow a patient to breathe ambient air in the event of a power failure. In one form, the patient interface **3000** includes an anti-asphyxia valve.

8.3.9 Ports

In one form of the present technology, a patient interface **3000** includes one or more ports that allow access to the volume within the plenum chamber **3200**. In one form this allows a clinician to supply supplemental oxygen. In one form, this allows for the direct measurement of a property of gases within the plenum chamber **3200**, such as the pressure.

8.4 RPT Device

An RPT device **4000** in accordance with one aspect of the present technology (as shown in FIG. **4**A) comprises mechanical and pneumatic components **4100**, electrical components **4200** and is configured to execute one or more algorithms **4300**. The RPT device may have an external housing **4010**, formed in two parts, an upper portion **4012** and a lower portion **4014**. Furthermore, the external housing **4010** may include one or more panel(s) **4015**. The RPT device **4000** comprises a chassis **4016** that supports one or more internal components of the RPT device **4000**. The RPT device **4000** may include a handle **4018**.

The pneumatic path of the RPT device **4000** may comprise one or more air path items, e.g., an inlet air filter **4112**, an inlet muffler **4122**, a pressure generator **4140** capable of supplying air at positive pressure (e.g., a blower **4142**), an outlet muffler **4124** and one or more transducers **4270**, such as pressure sensors **4272** and flow rate sensors **4274**.

One or more of the air path items may be located within a removable unitary structure which will be referred to as a pneumatic block **4020**. The pneumatic block **4020** may be located within the external housing **4010**. In one form a pneumatic block **4020** is supported by, or formed as part of the chassis **4016**.

The RPT device **4000** may have an electrical power supply **4210**, one or more input devices **4220**, a central controller **4230**, a therapy device controller **4240**, a pressure generator **4140**, one or more protection circuits **4250**, memory **4260**, transducers **4270**, data communication interface **4280** and one or more output devices **4290**. Electrical components **4200** may be mounted on a single Printed Circuit Board Assembly (PCBA) **4202**. In an alternative form, the RPT device **4000** may include more than one PCBA **4202**.

8.4.1 RPT Device Mechanical & Pneumatic Components

An RPT device may comprise one or more of the following components in an integral unit. In an alternative form, one or more of the following components may be located as respective separate units.

8.4.1.1 Air Filter(s)

An RPT device in accordance with one form of the present technology may include an air filter **4110**, or a plurality of air filters **4110**.

In one form, an inlet air filter **4112** is located at the beginning of the pneumatic path upstream of a pressure generator **4140**.

In one form, an outlet air filter **4114**, for example an antibacterial filter, is located between an outlet of the pneumatic block **4020** and a patient interface **3000**.

8.4.1.2 Pressure Generator

In one form of the present technology, a pressure generator **4140** for producing a flow, or a supply, of air at positive pressure is a controllable blower **4142**. For example the blower **4142** may include a brushless DC motor **4144** with one or more impellers housed in a volute. The blower may be capable of delivering a supply of air, for example at a rate of up to about 120 litres/minute, at a positive pressure in a range from about 4 cmH_2O to about 20 cmH_2O, or in other forms up to about 30 cmH_2O. The blower may be as described in any one of the following patents or patent applications the contents of which are incorporated herein by reference in their entirety: U.S. Pat. Nos. 7,866,944; 8,638,014; 8,636,479; and PCT Patent Application Publication No. WO 2013/020167.

The pressure generator **4140** is under the control of the therapy device controller **4240**.

In other forms, a pressure generator **4140** may be a piston-driven pump, a pressure regulator connected to a high pressure source (e.g. compressed air reservoir), or a bellows.

8.4.1.3 Air Circuit

An air circuit **4170** in accordance with an aspect of the present technology is a conduit or a tube constructed and arranged to allow, in use, a flow of air to travel between two components such as the RPT device **4000** and the patient interface **3000**.

In particular, the air circuit **4170** may be in fluid connection with the outlet of the RPT device **4000** and the patient interface **3000**. The air circuit may be referred to as an air delivery tube or conduit. In some cases there may be separate limbs of the circuit for inhalation and exhalation. In other cases a single limb is used.

In some forms, the air circuit **4170** may comprise one or more heating elements configured to heat air in the air circuit, for example to maintain or raise the temperature of the air. The heating element may be in a form of a heated wire circuit, and may comprise one or more transducers, such as temperature sensors. In one form, the heated wire circuit may be helically wound around the axis of the air circuit **4170**. The heating element may be in communication with a controller such as a central controller **4230**. One example of an air circuit **4170** comprising a heated wire circuit is described in U.S. Pat. No. 8,733,349, which is incorporated herewithin in its entirety by reference.

8.5 Humidifier

8.5.1 Humidifier Overview

In one form of the present technology there is provided a humidifier **5000** (e.g. as shown in FIG. **5**A) to change the absolute humidity of air or gas for delivery to a patient relative to ambient air. Typically, the humidifier **5000** is used to increase the absolute humidity and increase the temperature of the flow of air (relative to ambient air) before delivery to the patient's airways.

The humidifier **5000** may comprise a humidifier reservoir **5110**, a humidifier inlet **5002** to receive a flow of air, and a humidifier outlet **5004** to deliver a humidified flow of air. In some forms, as shown in FIG. **5**A and FIG. **5**B, an inlet and an outlet of the humidifier reservoir **5110** may be the humidifier inlet **5002** and the humidifier outlet **5004** respectively. The humidifier **5000** may further comprise a humidifier base **5006**, which may be adapted to receive the humidifier reservoir **5110** and comprise a heating element **5240**.

8.6 Glossary

For the purposes of the present technology disclosure, in certain forms of the present technology, one or more of the following definitions may apply. In other forms of the present technology, alternative definitions may apply.

8.6.1 General

Air: In certain forms of the present technology, air may be taken to mean atmospheric air, and in other forms of the present technology air may be taken to mean some other combination of breathable gases, e.g. atmospheric air enriched with oxygen.

Ambient: In certain forms of the present technology, the term ambient will be taken to mean (i) external of the treatment system or patient, and (ii) immediately surrounding the treatment system or patient.

For example, ambient humidity with respect to a humidifier may be the humidity of air immediately surrounding the humidifier, e.g. the humidity in the room where a patient is sleeping. Such ambient humidity may be different to the humidity outside the room where a patient is sleeping.

In another example, ambient pressure may be the pressure immediately surrounding or external to the body.

In certain forms, ambient (e.g., acoustic) noise may be considered to be the background noise level in the room where a patient is located, other than for example, noise generated by an RPT device or emanating from a mask or patient interface. Ambient noise may be generated by sources outside the room.

Automatic Positive Airway Pressure (APAP) therapy: CPAP therapy in which the treatment pressure is automatically adjustable, e.g. from breath to breath, between minimum and maximum limits, depending on the presence or absence of indications of SDB events.

Continuous Positive Airway Pressure (CPAP) therapy: Respiratory pressure therapy in which the treatment pressure is approximately constant through a respiratory cycle of a patient. In some forms, the pressure at the entrance to the airways will be slightly higher during exhalation, and slightly lower during inhalation. In some forms, the pressure will vary between different respiratory cycles of the patient, for example, being increased in response to detection of indications of partial upper airway obstruction, and decreased in the absence of indications of partial upper airway obstruction.

Flow rate: The volume (or mass) of air delivered per unit time. Flow rate may refer to an instantaneous quantity. In some cases, a reference to flow rate will be a reference to a scalar quantity, namely a quantity having magnitude only. In other cases, a reference to flow rate will be a reference to a vector quantity, namely a quantity having both magnitude and direction. Flow rate may be given the symbol Q. ‘Flow rate’ is sometimes shortened to simply ‘flow’.

In the example of patient respiration, a flow rate may be nominally positive for the inspiratory portion of a breathing cycle of a patient, and hence negative for the expiratory portion of the breathing cycle of a patient. Total flow rate, Qt, is the flow rate of air leaving the RPT device. Vent flow rate, Qv, is the flow rate of air leaving a vent to allow washout of exhaled gases. Leak flow rate, Ql, is the flow rate of leak from a patient interface system or elsewhere. Respiratory flow rate, Qr, is the flow rate of air that is received into the patient’s respiratory system.

Leak: The word leak will be taken to be an unintended flow of air. In one example, leak may occur as the result of an incomplete seal between a mask and a patient’s face. In another example leak may occur in a swivel elbow to the ambient.

Noise, conducted (acoustic): Conducted noise in the present document refers to noise which is carried to the patient by the pneumatic path, such as the air circuit and the patient interface as well as the air therein. In one form, conducted noise may be quantified by measuring sound pressure levels at the end of an air circuit.

Noise, radiated (acoustic): Radiated noise in the present document refers to noise which is carried to the patient by the ambient air. In one form, radiated noise may be quantified by measuring sound power/pressure levels of the object in question according to ISO 3744.

Noise, vent (acoustic): Vent noise in the present document refers to noise which is generated by the flow of air through any vents such as vent holes of the patient interface.

Patient: A person, whether or not they are suffering from a respiratory disease.

Pressure: Force per unit area. Pressure may be expressed in a range of units, including cmH_2O, g-f/cm^2 and hectopascal. 1 cmH_2O is equal to 1 g-f/cm^2 and is approximately 0.98 hectopascal. In this specification, unless otherwise stated, pressure is given in units of cmH_2O.

The pressure in the patient interface is given the symbol Pm, while the treatment pressure, which represents a target value to be achieved by the mask pressure Pm at the current instant of time, is given the symbol Pt.

Respiratory Pressure Therapy (RPT): The application of a supply of air to an entrance to the airways at a treatment pressure that is typically positive with respect to atmosphere.

Ventilator: A mechanical device that provides pressure support to a patient to perform some or all of the work of breathing.

8.6.1.1 Materials

Silicone or Silicone Elastomer: A synthetic rubber. In this specification, a reference to silicone is a reference to liquid silicone rubber (LSR) or a compression moulded silicone rubber (CMSR). One form of commercially available LSR is SILASTIC (included in the range of products sold under this trademark), manufactured by Dow Corning. Another manufacturer of LSR is Wacker. Unless otherwise specified to the contrary, an exemplary form of LSR has a Shore A (or Type A) indentation hardness in the range of about 35 to about 45 as measured using ASTM D2240.

Polycarbonate: a typically transparent thermoplastic polymer of Bisphenol-A Carbonate.

8.6.1.2 Mechanical Properties

Resilience: Ability of a material to absorb energy when deformed elastically and to release the energy upon unloading.

- ‘Resilient’: Will release substantially all of the energy when unloaded. Includes e.g. certain silicones, and thermoplastic elastomers.

Hardness: The ability of a material per se to resist deformation (e.g. described by a Young’s Modulus, or an indentation hardness scale measured on a standardised sample size).

- ‘Soft’ materials may include silicone or thermo-plastic elastomer (TPE), and may, e.g. readily deform under finger pressure.
- ‘Hard’ materials may include polycarbonate, polypropylene, steel or aluminium, and may not e.g. readily deform under finger pressure.

Stiffness (or rigidity) of a structure or component: The ability of the structure or component to resist deformation in response to an applied load. The load may be a force or a moment, e.g. compression, tension, bending or torsion. The structure or component may offer different resistances in different directions.

'Floppy' structure or component: A structure or component that will change shape, e.g. bend, when caused to support its own weight, within a relatively short period of time such as 1 second.

'Rigid' structure or component: A structure or component that will not substantially change shape when subject to the loads typically encountered in use. An example of such a use may be setting up and maintaining a patient interface in sealing relationship with an entrance to a patient's airways, e.g. at a load of approximately 20 to 30 cmH_2O pressure.

As an example, an I-beam may comprise a different bending stiffness (resistance to a bending load) in a first direction in comparison to a second, orthogonal direction. In another example, a structure or component may be floppy in a first direction and rigid in a second direction.

8.6.2 Respiratory Cycle

Apnea: According to some definitions, an apnea is said to have occurred when flow falls below a predetermined threshold for a duration, e.g. 10 seconds. An obstructive apnea will be said to have occurred when, despite patient effort, some obstruction of the airway does not allow air to flow. A central apnea will be said to have occurred when an apnea is detected that is due to a reduction in breathing effort, or the absence of breathing effort, despite the airway being patent. A mixed apnea occurs when a reduction or absence of breathing effort coincides with an obstructed airway.

Breathing rate: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

Duty cycle: The ratio of inhalation time, Ti to total breath time, Ttot.

Effort (breathing): The work done by a spontaneously breathing person attempting to breathe.

Expiratory portion of a breathing cycle: The period from the start of expiratory flow to the start of inspiratory flow.

Flow limitation: Flow limitation will be taken to be the state of affairs in a patient's respiration where an increase in effort by the patient does not give rise to a corresponding increase in flow. Where flow limitation occurs during an inspiratory portion of the breathing cycle it may be described as inspiratory flow limitation. Where flow limitation occurs during an expiratory portion of the breathing cycle it may be described as expiratory flow limitation.

Types of flow limited inspiratory waveforms:

(i) Flattened: Having a rise followed by a relatively flat portion, followed by a fall.

(ii) M-shaped: Having two local peaks, one at the leading edge, and one at the trailing edge, and a relatively flat portion between the two peaks.

(iii) Chair-shaped: Having a single local peak, the peak being at the leading edge, followed by a relatively flat portion.

(iv) Reverse-chair shaped: Having a relatively flat portion followed by single local peak, the peak being at the trailing edge.

Hypopnea: According to some definitions, a hypopnea is taken to be a reduction in flow, but not a cessation of flow. In one form, a hypopnea may be said to have occurred when there is a reduction in flow below a threshold rate for a duration. A central hypopnea will be said to have occurred when a hypopnea is detected that is due to a reduction in breathing effort. In one form in adults, either of the following may be regarded as being hypopneas:

(i) a 30% reduction in patient breathing for at least 10 seconds plus an associated 4% desaturation; or

(ii) a reduction in patient breathing (but less than 50%) for at least 10 seconds, with an associated desaturation of at least 3% or an arousal.

Hyperpnea: An increase in flow to a level higher than normal.

Inspiratory portion of a breathing cycle: The period from the start of inspiratory flow to the start of expiratory flow will be taken to be the inspiratory portion of a breathing cycle.

Patency (airway): The degree of the airway being open, or the extent to which the airway is open. A patent airway is open. Airway patency may be quantified, for example with a value of one (1) being patent, and a value of zero (0), being closed (obstructed).

Positive End-Expiratory Pressure (PEEP): The pressure above atmosphere in the lungs that exists at the end of expiration.

Peak flow rate (Qpeak): The maximum value of flow rate during the inspiratory portion of the respiratory flow waveform.

Respiratory flow rate, patient airflow rate, respiratory airflow rate (Qr): These terms may be understood to refer to the RPT device's estimate of respiratory airflow rate, as opposed to "true respiratory flow rate" or "true respiratory airflow rate", which is the actual respiratory flow rate experienced by the patient, usually expressed in litres per minute.

Tidal volume (Vt): The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied.

(inhalation) Time (Ti): The duration of the inspiratory portion of the respiratory flow rate waveform.

(exhalation) Time (Te): The duration of the expiratory portion of the respiratory flow rate waveform.

(total) Time (Ttot): The total duration between the start of one inspiratory portion of a respiratory flow rate waveform and the start of the following inspiratory portion of the respiratory flow rate waveform.

Typical recent ventilation: The value of ventilation around which recent values of ventilation Vent over some predetermined timescale tend to cluster, that is, a measure of the central tendency of the recent values of ventilation.

Upper airway obstruction (UAO): includes both partial and total upper airway obstruction. This may be associated with a state of flow limitation, in which the flow rate increases only slightly or may even decrease as the pressure difference across the upper airway increases (Starling resistor behaviour).

Ventilation (Vent): A measure of a rate of gas being exchanged by the patient's respiratory system. Measures of ventilation may include one or both of inspiratory and expiratory flow, per unit time. When expressed as a volume per minute, this quantity is often referred to as "minute ventilation". Minute ventilation is sometimes given simply as a volume, understood to be the volume per minute.

8.6.3 Ventilation

Adaptive Servo-Ventilator (ASV): A servo-ventilator that has a changeable, rather than fixed target ventilation. The changeable target ventilation may be learned from some characteristic of the patient, for example, a respiratory characteristic of the patient.

Backup rate: A parameter of a ventilator that establishes the minimum breathing rate (typically in number of breaths per minute) that the ventilator will deliver to the patient, if not triggered by spontaneous respiratory effort.

Cycled: The termination of a ventilator's inspiratory phase. When a ventilator delivers a breath to a spontaneously breathing patient, at the end of the inspiratory portion of the breathing cycle, the ventilator is said to be cycled to stop delivering the breath.

Expiratory positive airway pressure (EPAP): a base pressure, to which a pressure varying within the breath is added to produce the desired mask pressure which the ventilator will attempt to achieve at a given time.

End expiratory pressure (EEP): Desired mask pressure which the ventilator will attempt to achieve at the end of the expiratory portion of the breath. If the pressure waveform template $\Pi(\Phi)$ is zero-valued at the end of expiration, i.e. $\Pi(\Phi)=0$ when $\Phi=1$, the EEP is equal to the EPAP.

Inspiratory positive airway pressure (IPAP): Maximum desired mask pressure which the ventilator will attempt to achieve during the inspiratory portion of the breath.

Pressure support: A number that is indicative of the increase in pressure during ventilator inspiration over that during ventilator expiration, and generally means the difference in pressure between the maximum value during inspiration and the base pressure (e.g., PS=IPAP−EPAP). In some contexts pressure support means the difference which the ventilator aims to achieve, rather than what it actually achieves.

Servo-ventilator: A ventilator that measures patient ventilation, has a target ventilation, and which adjusts the level of pressure support to bring the patient ventilation towards the target ventilation.

Spontaneous/Timed (S/T): A mode of a ventilator or other device that attempts to detect the initiation of a breath of a spontaneously breathing patient. If however, the device is unable to detect a breath within a predetermined period of time, the device will automatically initiate delivery of the breath.

Swing: Equivalent term to pressure support.

Triggered: When a ventilator delivers a breath of air to a spontaneously breathing patient, it is said to be triggered to do so at the initiation of the respiratory portion of the breathing cycle by the patient's efforts.

Typical recent ventilation: The typical recent ventilation Vtyp is the value around which recent measures of ventilation over some predetermined timescale tend to cluster. For example, a measure of the central tendency of the measures of ventilation over recent history may be a suitable value of a typical recent ventilation.

8.6.4 Anatomy

8.6.4.1 Anatomy of the Face

Ala: the external outer wall or "wing" of each nostril (plural: alar)

Alare: The most lateral point on the nasal ala.

Alar curvature (or alar crest) point: The most posterior point in the curved base line of each ala, found in the crease formed by the union of the ala with the cheek.

Auricle: The whole external visible part of the ear.

(nose) Bony framework: The bony framework of the nose comprises the nasal bones, the frontal process of the maxillae and the nasal part of the frontal bone.

(nose) Cartilaginous framework: The cartilaginous framework of the nose comprises the septal, lateral, major and minor cartilages.

Columella: the strip of skin that separates the nares and which runs from the pronasale to the upper lip.

Columella angle: The angle between the line drawn through the midpoint of the nostril aperture and a line drawn perpendicular to the Frankfurt horizontal while intersecting subnasale.

Frankfort horizontal plane: A line extending from the most inferior point of the orbital margin to the left tragion. The tragion is the deepest point in the notch superior to the tragus of the auricle.

Glabella: Located on the soft tissue, the most prominent point in the midsagittal plane of the forehead.

Lateral nasal cartilage: A generally triangular plate of cartilage. Its superior margin is attached to the nasal bone and frontal process of the maxilla, and its inferior margin is connected to the greater alar cartilage.

Lip, lower (labrale inferius):

Lip, upper (labrale superius):

Greater alar cartilage: A plate of cartilage lying below the lateral nasal cartilage. It is curved around the anterior part of the naris. Its posterior end is connected to the frontal process of the maxilla by a tough fibrous membrane containing three or four minor cartilages of the ala.

Nares (Nostrils): Approximately ellipsoidal apertures forming the entrance to the nasal cavity. The singular form of nares is naris (nostril). The nares are separated by the nasal septum.

Naso-labial sulcus or Naso-labial fold: The skin fold or groove that runs from each side of the nose to the corners of the mouth, separating the cheeks from the upper lip.

Naso-labial angle: The angle between the columella and the upper lip, while intersecting subnasale.

Otobasion inferior: The lowest point of attachment of the auricle to the skin of the face.

Otobasion superior: The highest point of attachment of the auricle to the skin of the face.

Pronasale: the most protruded point or tip of the nose, which can be identified in lateral view of the rest of the portion of the head.

Philtrum: the midline groove that runs from lower border of the nasal septum to the top of the lip in the upper lip region.

Pogonion: Located on the soft tissue, the most anterior midpoint of the chin.

Ridge (nasal): The nasal ridge is the midline prominence of the nose, extending from the Sellion to the Pronasale.

Sagittal plane: A vertical plane that passes from anterior (front) to posterior (rear) dividing the body into right and left halves.

Sellion: Located on the soft tissue, the most concave point overlying the area of the frontonasal suture.

Septal cartilage (nasal): The nasal septal cartilage forms part of the septum and divides the front part of the nasal cavity.

Subalare: The point at the lower margin of the alar base, where the alar base joins with the skin of the superior (upper) lip.

Subnasal point: Located on the soft tissue, the point at which the columella merges with the upper lip in the midsagittal plane.

Supramentale: The point of greatest concavity in the midline of the lower lip between labrale inferius and soft tissue pogonion

8.6.4.2 Anatomy of the Skull

Frontal bone: The frontal bone includes a large vertical portion, the squama frontalis, corresponding to the region known as the forehead.

Mandible: The mandible forms the lower jaw. The mental protuberance is the bony protuberance of the jaw that forms the chin.

Maxilla: The maxilla forms the upper jaw and is located above the mandible and below the orbits. The frontal process of the maxilla projects upwards by the side of the nose, and forms part of its lateral boundary.

Nasal bones: The nasal bones are two small oblong bones, varying in size and form in different individuals; they are placed side by side at the middle and upper part of the face, and form, by their junction, the "bridge" of the nose.

Nasion: The intersection of the frontal bone and the two nasal bones, a depressed area directly between the eyes and superior to the bridge of the nose.

Occipital bone: The occipital bone is situated at the back and lower part of the cranium. It includes an oval aperture, the foramen magnum, through which the cranial cavity communicates with the vertebral canal. The curved plate behind the foramen magnum is the squama occipitalis.

Orbit: The bony cavity in the skull to contain the eyeball.

Parietal bones: The parietal bones are the bones that, when joined together, form the roof and sides of the cranium.

Temporal bones: The temporal bones are situated on the bases and sides of the skull, and support that part of the face known as the temple.

Zygomatic bones: The face includes two zygomatic bones, located in the upper and lateral parts of the face and forming the prominence of the cheek.

8.6.4.3 Anatomy of the Respiratory System

Diaphragm: A sheet of muscle that extends across the bottom of the rib cage. The diaphragm separates the thoracic cavity, containing the heart, lungs and ribs, from the abdominal cavity. As the diaphragm contracts the volume of the thoracic cavity increases and air is drawn into the lungs.

Larynx: The larynx, or voice box houses the vocal folds and connects the inferior part of the pharynx (hypopharynx) with the trachea.

Lungs: The organs of respiration in humans. The conducting zone of the lungs contains the trachea, the bronchi, the bronchioles, and the terminal bronchioles. The respiratory zone contains the respiratory bronchioles, the alveolar ducts, and the alveoli.

Nasal cavity: The nasal cavity (or nasal fossa) is a large air filled space above and behind the nose in the middle of the face. The nasal cavity is divided in two by a vertical fin called the nasal septum. On the sides of the nasal cavity are three horizontal outgrowths called nasal conchae (singular "concha") or turbinates. To the front of the nasal cavity is the nose, while the back blends, via the choanae, into the nasopharynx.

Pharynx: The part of the throat situated immediately inferior to (below) the nasal cavity, and superior to the oesophagus and larynx. The pharynx is conventionally divided into three sections: the nasopharynx (epipharynx) (the nasal part of the pharynx), the oropharynx (mesopharynx) (the oral part of the pharynx), and the laryngopharynx (hypopharynx).

8.6.5 Patient Interface

Anti-asphyxia valve (AAV): The component or sub-assembly of a mask system that, by opening to atmosphere in a failsafe manner, reduces the risk of excessive CO_2 rebreathing by a patient.

Elbow: An elbow is an example of a structure that directs an axis of flow of air travelling therethrough to change direction through an angle. In one form, the angle may be approximately 90 degrees. In another form, the angle may be more, or less than 90 degrees. The elbow may have an approximately circular cross-section. In another form the elbow may have an oval or a rectangular cross-section. In certain forms an elbow may be rotatable with respect to a mating component, e.g. about 360 degrees. In certain forms an elbow may be removable from a mating component, e.g. via a snap connection. In certain forms, an elbow may be assembled to a mating component via a one-time snap during manufacture, but not removable by a patient.

Frame: Frame will be taken to mean a mask structure that bears the load of tension between two or more points of connection with a headgear. A mask frame may be a non-airtight load bearing structure in the mask. However, some forms of mask frame may also be air-tight.

Headgear: Headgear will be taken to mean a form of positioning and stabilizing structure designed for use on a head. For example the headgear may comprise a collection of one or more struts, ties and stiffeners configured to locate and retain a patient interface in position on a patient's face for delivery of respiratory therapy. Some ties are formed of a soft, flexible, elastic material such as a laminated composite of foam and fabric.

Membrane: Membrane will be taken to mean a typically thin element that has, preferably, substantially no resistance to bending, but has resistance to being stretched.

Plenum chamber: a mask plenum chamber will be taken to mean a portion of a patient interface having walls at least partially enclosing a volume of space, the volume having air therein pressurised above atmospheric pressure in use. A shell may form part of the walls of a mask plenum chamber.

Seal: May be a noun form ("a seal") which refers to a structure, or a verb form ("to seal") which refers to the effect. Two elements may be constructed and/or arranged to 'seal' or to effect 'sealing' therebetween without requiring a separate 'seal' element per se.

Shell: A shell will be taken to mean a curved, relatively thin structure having bending, tensile and compressive stiffness. For example, a curved structural wall of a mask may be a shell. In some forms, a shell may be faceted. In some forms a shell may be airtight. In some forms a shell may not be airtight.

Stiffener: A stiffener will be taken to mean a structural component designed to increase the bending resistance of another component in at least one direction.

Strut: A strut will be taken to be a structural component designed to increase the compression resistance of another component in at least one direction.

Swivel (noun): A subassembly of components configured to rotate about a common axis, preferably independently, preferably under low torque. In one form, the swivel may be constructed to rotate through an angle of at least 360 degrees. In another form, the swivel may be constructed to rotate through an angle less than 360 degrees. When used in the context of an air delivery conduit, the sub-assembly of components preferably comprises a matched pair of cylindrical conduits. There may be little or no leak flow of air from the swivel in use.

Tie (noun): A structure designed to resist tension.

Vent: (noun): A structure that allows a flow of air from an interior of the mask, or conduit, to ambient air for clinically effective washout of exhaled gases. For example, a clinically effective washout may involve a flow rate of about 10 litres per minute to about 100 litres per minute, depending on the mask design and treatment pressure.

8.7 Other Remarks

reproduction by anyone of the patent document or the patent disclosure, as it appears in Patent Office patent files or records, but otherwise reserves all copyright rights whatsoever.

Unless the context clearly dictates otherwise and where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, between the upper and lower limit of that range, and any other stated or intervening value in that stated range is encompassed within the technology. The upper and lower limits of these intervening ranges, which may be independently included in the intervening ranges, are also encompassed within the technology, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the technology.

Furthermore, where a value or values are stated herein as being implemented as part of the technology, it is understood that such values may be approximated, unless otherwise stated, and such values may be utilized to any suitable significant digit to the extent that a practical technical implementation may permit or require it.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this technology belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present technology, a limited number of the exemplary methods and materials are described herein.

When a particular material is identified as being used to construct a component, obvious alternative materials with similar properties may be used as a substitute. Furthermore, unless specified to the contrary, any and all components herein described are understood to be capable of being manufactured and, as such, may be manufactured together or separately.

It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include their plural equivalents, unless the context clearly dictates otherwise.

All publications mentioned herein are incorporated herein by reference in their entirety to disclose and describe the methods and/or materials which are the subject of those publications. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present technology is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

The terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

The subject headings used in the detailed description are included only for the ease of reference of the reader and should not be used to limit the subject matter found throughout the disclosure or the claims. The subject headings should not be used in construing the scope of the claims or the claim limitations.

Although the technology herein has been described with reference to particular examples, it is to be understood that these examples are merely illustrative of the principles and applications of the technology. In some instances, the terminology and symbols may imply specific details that are not required to practice the technology. For example, although the terms “first” and “second” may be used, unless otherwise specified, they are not intended to indicate any order but may be utilised to distinguish between distinct elements. Furthermore, although process steps in the methodologies may be described or illustrated in an order, such an ordering is not required. Those skilled in the art will recognize that such ordering may be modified and/or aspects thereof may be conducted concurrently or even synchronously.

It is therefore to be understood that numerous modifications may be made to the illustrative examples and that other arrangements may be devised without departing from the spirit and scope of the technology.

8.8 Reference Signs List

1000 Patient
1100 Bed partner
3000 Patient interface
3100 Sealing or seal-forming structure
3150 Cushion assembly
3170 Nasal seal-forming structure
3180 Oral seal-forming structure
3200 Plenum chamber
3210 Plenum chamber perimeter
3300 Positing and stabilising structure/headgear
3310 Headgear strap
3320 Chin strap
3330 Padded members
3340 Elastic sleeves
3342 Side opening
3343 Top opening
3345 Tab
3347 Rounded edges
3348 Patient contacting side
3349 Non-patient contacting side
3350 Headgear tube
3351 Upper tube member
3352 Tube ends
3353A Upper curved portion
3353B Lower curved portion
3354 Less stretchable tube section
3355 More stretchable tube section
3356 Securing mechanism
3357 First securing member
3358 Second securing member
3360 Adjustment mechanism
3362 Concertina tube section
3363 Non-adjustable headgear tube section
3364 Fold portion
3366 Tube wall fold/rolling fold portion
3368 Adjacent tube portion
3370 First tube portion
3371 First tab
3372 Second tube portion
3373 Second tab
3374 Ribs
3375 Nested concentric tube sections
3376 Ratchet mechanism
3377 Visual indicator
3378 Button
3379 Rigidising members
3380 First threaded portion
3382 Second threaded portion
3383 Pinion

3384 Ring member
3385 Replaceable tube portion
3386 Replacement tube portions
3387 Tube insert member
3390 Strap
3391 Strap adjustment mechanism
3395 Band
3397 Tongue
3398 Grooves
3410 Loop insert member
3411 Replacement loop insert members
3420 Inflatable loop insert member
3600 Connection port
3744 ISO
4000 RPT device
4010 External housing
4012 Upper portion
4014 Portion
4015 Panel
4016 Chassis
4018 Handle
4020 Pneumatic block
4100 Pneumatic components
4110 Air filter
4112 Inlet air filter
4114 Outlet air filter
4122 Inlet muffler
4124 Outlet muffler
4140 Pressure generator
4142 Controllable blower
4144 Brushless DC motor
4170 Air circuit
4200 Electrical components
4202 Printed Circuit Board Assembly (PCBA)
4210 Electrical power supply
4220 Input devices
4230 Central controller
4240 Therapy device controller
4250 Protection circuits
4260 Memory
4270 Transducers
4272 Pressure sensors
4274 Flow rate sensors
4280 Data communication interface
4290 Output devices
4300 Algorithms
5000 Humidifier
5002 Humidifier inlet
5004 Humidifier outlet
5006 Humidifier base
5110 Humidifier reservoir
5130 Humidifier reservoir dock
5240 Heating element
6000 Force-extension plot
6100 Extension axis
6105 Zero extension
6110 First amount of extension
6120 Second amount of extension
6200 Force axis
6210 Minimum sealing force
6220 Maximum comfort force
6300 Force-extension characteristic

The invention claimed is:

1. A patient interface for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use, the patient interface comprising:

a cushion assembly comprising:

a plenum chamber pressurisable to the therapeutic pressure, said plenum chamber including a pair of plenum chamber inlet ports, each of the plenum chamber inlet ports being sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient; and

a seal-forming structure constructed and arranged to seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use;

a positioning and stabilising structure configured to hold the seal-forming structure in a therapeutically effective position on a head of a patient, the positioning and stabilising structure comprising:

two gas delivery tubes, each of the two gas delivery tubes being connected to a corresponding one of plenum chamber inlet ports to deliver the flow of air to the entrance to the patient's airways via the cushion assembly, each of the two gas delivery tubes being configured to be positioned on a corresponding lateral side of the patient's head in use, at least one of the gas delivery tubes having a tab projecting outwardly therefrom in a generally posterior direction relative to the patient's head in use, the tab having a hole, and each of the two gas delivery tubes being constructed and arranged to contact, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head;

a bias and adjustment mechanism configured to allow adjustment of a length of each of the two gas delivery tubes to enable the length of each of the two gas delivery tubes to be adjusted through a continuous range of lengths to fit different size heads, and the bias and adjustment mechanism being configured to impart a biasing force along at least a part of a length of each of the two gas delivery tubes to urge the seal-forming structure towards the entrance to the patient's airways in use;

a length-adjustable rear strap, an end of the length-adjustable rear strap being configured to pass through the hole of the tab to removably connect the length-adjustable rear strap to the gas delivery tube and the length-adjustable rear strap being configured, in use, to pass around a posterior portion of the patient's head; and

a connection port configured to fluidly connect, in use, the gas delivery tubes with an air circuit to deliver the flow of air to the patient's airways, the connection port configured to be located, in use, superior to the patient's head,

wherein each of the two gas delivery tubes comprises a first end configured to be connected to the cushion assembly,

wherein the bias and adjustment mechanism comprises an elastic member formed on each of the gas delivery tubes between the corresponding first end and the connection port,

wherein the elastic member comprises a portion of the gas delivery tube having a concertina structure,

wherein the portion of the gas delivery tube having the concertina structure is, in use, positioned in contact with a region of the patient's head superior to the patient's otobasion superior, and

wherein the tab is positioned on the gas delivery tube between the portion of the gas delivery tube having the concertina structure and the first end.

2. A patient interface as claimed in claim **1**, further comprising an elastic sleeve covering each of the two gas delivery tubes.

3. A patient interface as claimed in claim **2**, wherein the elastic sleeve is formed from an elastic material.

4. A patient interface as claimed in claim **1**, wherein the positioning and stabilising structure is configured such that, in use, the bias and adjustment mechanism is positioned so as not to contact the patient's face.

5. A patient interface as claimed in claim **1**, wherein the positioning and stabilising structure is configured such that, in use, the bias and adjustment mechanism is positioned so as not to contact the patient's cheek region.

6. A patient interface as claimed in claim **1**, wherein the positioning and stabilising structure is configured such that, in use, the bias and adjustment mechanism is positioned superior to the otobasion superior of the patient's head.

7. A patient interface as claimed in claim **1**, wherein each of the gas delivery tubes is configured to extend, in use, across the patient's corresponding cheek region.

8. A patient interface as claimed in claim **1**, wherein the positioning and stabilising structure is free of any mechanisms for enabling length adjustment of each of the two gas delivery tubes at a portion of each of the gas delivery tubes that is configured to contact the patient's head inferior to the otobasion superior of the patient's head.

9. A patient interface as claimed in claim **1**, wherein the positioning and stabilising structure is free of any mechanisms for enabling length adjustment of each of the two gas delivery tubes at a portion of each of the gas delivery tubes that is configured to extend, in use, across the patient's cheek regions.

10. A patient interface as claimed in claim **1**, wherein each of the two gas delivery tubes is configured to extend, in use, between the patient's corresponding eye and the patient's corresponding ear.

11. A patient interface as claimed in claim **1**, wherein an angle of the length-adjustable rear strap relative to each of the gas delivery tubes is adjustable to allow the length-adjustable rear strap to fit around the patient's head at a different locations.

12. A patient interface as claimed in claim **1**, wherein the bias and adjustment mechanism is configured to be positioned, in use, above a point of connection of the length-adjustable rear strap to each of the two gas delivery tubes, and the positioning and stabilising structure is free of any mechanisms for enabling length adjustment of each of the two gas delivery tubes positioned below the point of connection of the length-adjustable rear strap to each of the two gas delivery tubes.

13. A patient interface as claimed in claim **1**, wherein the length-adjustable rear strap comprises a loop material and a hook material portion, the loop material and the hook material portion being configured to removably connect the length-adjustable rear strap to the tab.

14. A patient interface as claimed in claim **1**, wherein each of the two gas delivery tubes varies in width and diameter along the length of each concertina structure.

15. A patient interface as claimed in claim **14**, wherein each of the two gas delivery tubes tapers along the length of each concertina structure so that the width and diameter of each of the two gas delivery tubes at one end of the concertina structure is smaller than the width and diameter of each of the two gas delivery tubes at the other end of concertina structure.

16. A patient interface as claimed in claim **1**, further comprising an elbow including a first end rotatably connected to the positioning and stabilising structure at the connection port and a second end having a swivel configured to be connected to the air circuit, the elbow being rotatable 360° about the connection port, the swivel being rotatable 360° about the second end of the elbow, and the elbow being configured to direct the flow of air from the air circuit to the gas delivery tubes via the connection port.

17. A patient interface as claimed in claim **1**, further comprising:

an elastic sleeve covering each of the two gas delivery tubes, the elastic sleeve being formed from an elastic material; and

an elbow including a first end rotatably connected to the positioning and stabilising structure at the connection port and a second end having a swivel configured to be connected to the air circuit, the elbow being rotatable 360° about the connection port, the swivel being rotatable 360° about the second end of the elbow, and the elbow being configured to direct the flow of air from the air circuit to the gas delivery tubes via the connection port,

wherein the positioning and stabilising structure is configured such that, in use, the bias and adjustment mechanism is positioned so as not to contact the patient's face,

wherein each of the two gas delivery tubes is configured to extend, in use, between the patient's corresponding eye and the patient's corresponding ear,

wherein the length-adjustable rear strap comprises a loop material and a hook material portion, the loop material and the hook material portion being configured to removably connect the length-adjustable rear strap to the tab,

wherein each of the two gas delivery tubes varies in width and diameter along the length of each concertina structure, and

wherein each of the two gas delivery tubes tapers along the length of each concertina structure so that the width and diameter of each of the two gas delivery tubes at one end of the concertina structure is smaller than the width and diameter of each of the two gas delivery tubes at the other end of concertina structure.

18. A patient interface as claimed in claim **1**, wherein the tab is positioned on each of the two gas delivery tubes between a lower end of the portion of the gas delivery tube having the concertina structure and the first end.

19. A patient interface as claimed in claim **1**, wherein each of the gas delivery tubes includes the tab projecting outwardly therefrom in a generally posterior direction relative to the patient's head in use,

wherein each end of the length-adjustable rear strap is configured to pass through the hole of a corresponding tab to removably connect the length-adjustable rear strap to the gas delivery tube, and

wherein each tab is positioned on the corresponding gas delivery tube between the portion of the gas delivery tube having the concertina structure and the first end.

20. A patient interface for sealed delivery of a flow of air at a therapeutic pressure of at least 4 cmH_2O with respect to ambient air pressure throughout the patient's respiratory cycle in use, the patient interface comprising:

a cushion assembly comprising:

a plenum chamber pressurisable to the therapeutic pressure, said plenum chamber including a pair of plenum chamber inlet ports, each of the plenum chamber inlet ports being sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient; and

a seal-forming structure constructed and arranged to seal with a region of the patient's face surrounding an entrance to the patient's airways such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use;

a positioning and stabilising structure configured to hold the seal-forming structure in a therapeutically effective position on a head of a patient, the positioning and stabilising structure comprising:

two gas delivery tubes, each of the gas delivery tubes being connected at a first end to a corresponding one of plenum chamber inlet ports to deliver the flow of air to the entrance to the patient's airways, each of the gas delivery tubes being configured to be positioned on a corresponding lateral side of the patient's head in use, at least one of the gas delivery tubes having a tab projecting outwardly therefrom in a generally posterior direction relative to the patient's head in use, the tab having a hole, each of the gas delivery tubes being constructed and arranged to contact, in use, at least a region of the patient's head superior to an otobasion superior of the patient's head, each of the gas delivery tubes including a concertina section configured to allow length adjustment of the corresponding gas delivery tube through a continuous range of lengths to fit different size heads, and the concertina section being configured to impart a biasing force along the corresponding gas delivery tube to urge the cushion assembly against the patient's face in use;

a length-adjustable rear strap, an end of the length-adjustable rear strap being configured to pass through the hole of the tab to removably connect the length-adjustable rear strap to the gas delivery tube to the two gas delivery tubes and the length-adjustable rear strap being configured, in use, to engage a posterior portion of the patient's head; and

a connection port configured to fluidly connect, in use, the gas delivery tubes with an air circuit to deliver the flow of air to the patient's airways, the connection port being configured to be located, in use, superior to the patient's head,

wherein the concertina section being positioned between the corresponding first end and the connection port to contact a region of the patient's head superior to the patient's otobasion superior in use, and

wherein the tab is positioned on the gas delivery tube between the concertina section and the first end.

21. A patient interface as claimed in claim **20**, further comprising an elastic sleeve covering each of the two gas delivery tubes, the elastic sleeve being formed from an elastic material.

22. A patient interface as claimed in claim **20**, wherein an angle of the length-adjustable rear strap relative to each of the gas delivery tubes is adjustable to allow the length-adjustable rear strap to fit around the patient's head at a different locations.

23. A patient interface as claimed in claim **20**, wherein the positioning and stabilising structure is configured such that, in use, the concertina section is positioned so as not to contact the patient's face.

24. A patient interface as claimed in claim **20**, wherein each of the two gas delivery tubes is configured to extend, in use, between the patient's corresponding eye and the patient's corresponding ear.

25. A patient interface as claimed in claim **20**, wherein the length-adjustable rear strap comprises a loop material and a hook material portion, the loop material and the hook material portion being configured to removably connect the length-adjustable rear strap to the tab.

26. A patient interface as claimed in claim **20**, further comprising an elbow including a first end rotatably connected to the positioning and stabilising structure at the connection port and a second end having a swivel configured to be connected to the air circuit, the elbow being rotatable 360° about the connection port, the swivel being rotatable 360° about the second end of the elbow, and the elbow being configured to direct the flow of air from the air circuit to the gas delivery tubes via the connection port.

27. A patient interface as claimed in claim **20**, wherein each of the two gas delivery tubes tapers along the length of each concertina section so that the width and diameter of each of the two gas delivery tubes at one end of the concertina section is smaller than the width and diameter of each of the two gas delivery tubes at the other end of the concertina section.

28. A patient interface as claimed in claim **20**, further comprising:

an elastic sleeve covering each of the two gas delivery tubes; and

an elbow including a first end rotatably connected to the positioning and stabilising structure at the connection port and a second end having a swivel configured to be connected to the air circuit, the elbow being rotatable 360° about the connection port, the swivel being rotatable 360° about the second end of the elbow, and the elbow being configured to direct the flow of air from the air circuit to the gas delivery tubes via the connection port,

wherein the elastic sleeve is formed from an elastic material,

wherein the positioning and stabilising structure is configured such that, in use, the concertina section is positioned so as not to contact the patient's face,

wherein each of the two gas delivery tubes is configured to extend, in use, between the patient's corresponding eye and the patient's corresponding ear,

wherein the length-adjustable rear strap comprises a loop material and a hook material portion, the loop material and the hook material portion being configured to removably connect the length-adjustable rear strap to the tab, and

wherein each of the two gas delivery tubes tapers along the length of each concertina section so that the width and diameter of each of the two gas delivery tubes at one end of the concertina section is smaller than the width and diameter of each of the two gas delivery tubes at the other end of the concertina section.

29. A patient interface as claimed in claim **20**, wherein the tab is positioned on each of the two gas delivery tubes between a lower end of the concertina section and the corresponding first end.

30. A patient interface as claimed in claim **20**, wherein each of the gas delivery tubes includes the tab projecting outwardly therefrom in a generally posterior direction relative to the patient's head in use,

wherein each end of the length-adjustable rear strap is configured to pass through the hole of a corresponding tab to removably connect the length-adjustable rear strap to the gas delivery tube, and

wherein each tab is positioned on the corresponding gas delivery tube between the portion of the gas delivery tube having the concertina section and the first end.

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